THE STATUS OF IMPLEMENTATION OF THE FOOD QUALITY PROTECTION ACT OF 1996

HEARING

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT AND HAZARDOUS MATERIALS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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THE STATUS OF IMPLEMENTATION OF THE FOOD QUALITY PROTECTION ACT OF 1996

MONDAY, MARCH 25, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON ENVIRONMENT
AND HAZARDOUS MATERIALS,
Bowling Green, OH.

The subcommittee met, pursuant to notice, at 10:21 a.m., in the Commissioners' Hearing Room, Fifth floor, Wood County Courthouse, 1 Courthouse Square, Bowling Green, Ohio, Hon. Paul Gillmor (chairman) presiding.

Member present: Representative Gillmor.

Staff present: Amit Sachdev, majority counsel; Jerry Couri, policy coordinator; Hollyn Kidd, legislative clerk; and John Ford, minority counsel.

Mr. GILLMOR. I will call our first panel which right now consists of Dr. Brown. Would you come forward?

The subcommittee will now come to order and I want to express my thanks to everyone who came here today, either to testify or to lend support for those who are speaking or just to get yourself better informed about the issues which are surrounding the implementation of this very important food safety law.

We do not have our witness from EPA yet because of the weather. If they arrive, we will put them on the panel, or if they get here later, we will take their testimony after we have concluded the second panel. The weather, of course, is something we cannot control. Congress is out of session this week, so that gives us an opportunity to get around the District and we have a full schedule of 4 days and nine counties and now we have got this weather forecast for 3 days. So maybe it will be three counties, I am not sure.

This is the first of what may be a series of field hearings across the country on this and other health safety issues.

Before we get started with today's proceedings, I want to express my gratitude to Wood County Commissioner Tim Brown and to all of the County Commissioners for their hospitality. Jimmy Carter, the President of the County Commissioners, is in the back. Tim helped us secure the use of the facilities here and Tim used to be on my staff, so I am glad to see that I still know such an influential person.

I think it is fitting that we are in Ohio to discuss the implementation of the Food Quality Protection Act. In our state, really within the northwest corner of this state, we see the nexus of the issues facing the application of this new law and the many interests that

are working to see that the final regulations of this law are reasonable in their scope and effective in their outcome.

Six years ago, back in 1996, I was a co-sponsor of a bill that eventually became this law. The passage of the Food Quality Protection Act was a significant legislative achievement because it finally updated the Nation's food safety laws to reflect the decades worth of advances in science, medicine and agriculture. It was not a perfect bill by any means, and of course hardly ever any legislation ever is. But it did reflect a bipartisan compromise to establish a new risk assessment standard of reasonable certainty of no harm.

Our committee still has work to go in order to ensure that the statute is properly implemented. The goal today remains the same as it was when our committee first passed this bill and that is to ensure that the Act improves the safety of our food supply, instills confidence in the food quality of the United States and makes realistic risk-based demands on America's farmers.

And as we approach the second major statutory deadline of this Act, which comes on August 3 of this year, I am committed to overseeing FQPA implementation and I intend to continue to make it a priority of the Subcommittee of Environment and Hazardous Material.

Since it has been some time now since the Food Quality Protection Act was signed into law, I believe it is fair to look at the progress and the practical effects of the law. Although simply stated, the Food Quality Protection Act of 1996 amended Federal pesticide and food and drug laws by directing the EPA to apply improved standards to evaluate the safety of pesticides that are used on food crops including fruits, vegetables and grain, the last 6 years have seen both the U.S. EPA and the U.S. Department of Agriculture working hard to meet the rigorous statutory deadlines and struggling to develop new scientific models and methods for assessing pesticide risks.

The Food Quality Protection Act requires that EPA and USDA re-evaluate the maximum safe level for pesticide residues on food or tolerances by taking into consideration sensitivities of infants and children and by using the best available information to evaluate other important factors. In many respects, this process is scientifically complex and is often difficult for those of us who are non-scientists to follow.

Although my twin boys, who are five, are past the infant stage, as a concerned father, I know that proper implementation of FQPA is essential to dramatically impacting American farming and consumer confidence in food safety.

We have a very distinguished panel of government witnesses and Ohioans who are farmers, scientists, business people and citizens whose lives, health and livelihoods are impacted by the implementation of this Federal law. I look forward to hearing their oral remarks and posing the kind of questions that bill writers need to have for feedback from the law's affected stakeholders.

At this point, I want to introduce some of the other people up at this table so you know who they are. Jerry Couri, who is policy coordinator to the Environment and Hazardous Materials Subcommittee; Amit Sachdev, who is counsel to the full Energy and Commerce Committee; John Ford, who is minority counsel to the

Energy and Commerce Committee; and Hollyn Kidd, who is our legislative clerk.

[The prepared statement of Hon. Paul Gillmor follows:]

PREPARED STATEMENT OF HON. PAUL GILLMOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

The Subcommittee will now come to order. I want to express my thanks to everyone who has come here today, either to testify before our committee, lend support to those speaking, or just to get yourself better informed on the issues surrounding implementation of this important food safety law.

Before we get going with today's proceedings, I also want to acknowledge my gratitude to Wood County Commissioner Tim Brown. Tim helped us secure use of the facilities here in the Courthouse, and since he used to be on my staff, I am glad to be on good terms with such an influential figure.

I believe it is fitting that we are in Ohio to discuss the implementation of the Food Quality Protection Act. In our state, really within the Northwestern corner of the state, we see the nexus of the issues facing the application of this new law and the many interests that are working to see that the final regulations of this law are reasonable in their scope and effective in their outcome.

Six years ago, back in 1996, I was a cosponsor of the bill that eventually became this law. The passage of the Food Quality Protection Act was a significant legislative achievement because it finally updated the nation's food safety laws to reflect decades-worth of advances in science, medicine, and agriculture. It was not a perfect bill, by any means—although what legislation ever is, but it did reflect a bipartisan compromise to do away with the outdated Delaney Clause's "zero risk" standard with a new risk assessment standard of "reasonable certainty of no harm." Our Committee still has work to do in order to ensure that the statute is properly implemented. The goal today remains the same as it was when our Committee first passed this bill: ensure that the Act improves the safety of our food supply, instills confidence in the food quality of the United States, and makes realistic, risk-based demands on America's farmers. As we approach the second major statutory deadline of this Act on August 3, 2002, I am committed to overseeing FQPA implementation and I intend to continue to make it a priority for the Subcommittee on Environment and Hazardous Materials.

Since it has been some time since FQPA was signed into law, I believe it is fair to look at the progress and the practical effects of the law. Although, simply stated, the Food Quality Protection Act of 1996 amended federal pesticide and food and drug laws by directing EPA to apply improved standards to evaluate the safety of pesticides that are used on food crops, including as fruits, vegetables and grains; the last six years have seen both the U.S. Environmental Protection Agency and the U.S. Department of Agriculture working hard to meet the rigorous statutory deadlines and struggling to develop new scientific models and methods for assessing pesticide risks.

FQPA requires EPA and USDA to reevaluate the maximum safe levels for pesticide residues on foods, or "tolerances," by taking into consideration sensitivities of infants and children, and by using the best available information to evaluate other important factors. In many respects, this process is scientifically complex and is often difficult for non-scientists to follow. Although my twin boys are well passed the infant stage, as a concerned father, I know that proper implementation of FQPA is essential to dramatically impacting American farming and consumer confidence in food safety.

We have a very distinguished panel of government witnesses and Ohioans who are farmers, scientists, business people and citizens whose lives, health, and livelihoods are impacted by the implementation of this Federal law. I look forward to hearing each of their oral remarks and posing the kinds of questions that bill writers need to have feedback on from the law's affected stakeholders.

Again, thank you all for coming.

Mr. GILLMOR. Our first witness this morning is the Honorable Rodney Brown, who is Deputy Under Secretary of the United States Department of Agriculture from Washington. Dr. Brown.

STATEMENT OF HON. RODNEY J. BROWN, DEPUTY UNDER SECRETARY, U.S. DEPARTMENT OF AGRICULTURE

Mr. BROWN. Thank you, Chairman Gillmor, for the opportunity to appear today. My name is Rodney Brown and I am Deputy Under Secretary for Research, Education and Economics in the Department of Agriculture. I am pleased to discuss the role of USDA in implementing the Food Quality Protection Act of 1996. We are approaching the sixth anniversary of FQPA on August 3, which is also the statutory deadline requiring reassessment of two-thirds of all food tolerances that were in effect at the time the law was enacted. Throughout these first nearly 6 years of implementation, USDA has worked closely with the Environmental Protection Agency to ensure a sound scientific basis for regulatory decisions. Sound science must be based on high quality data and providing such data to EPA has been one of USDA's principal roles.

We have also worked in partnership with EPA, to ensure that our agricultural producers and crop production experts in the land-grant universities are active participants in supporting the regulatory process. Through these efforts, we have helped refine EPA's risk assessments and, when required, helped craft regulatory strategies that make sense to farmers, reduce the estimated risk and preserve many important uses of pesticide chemicals.

Although FQPA placed a number of demands on USDA, the challenges presented to EPA are even more demanding. EPA has successfully pushed the frontiers of risk assessment science and done an impressive job of dealing with the concepts of aggregate and cumulative risk. Along the way, EPA had to establish new science policies to guide state-of-the-art risk assessment methods. We appreciate EPA's efforts as well as the open and transparent processes they have used in decisionmaking. We look forward to a continuing partnership with EPA in implementation of the FQPA.

The Office of Pest Management Policy was created in September 1997 to help the Department respond to the demands of FQPA. OPMP has Department-wide responsibility and works across all USDA agencies. OPMP relies on Agricultural Research Service and Cooperative State Research, Education and Extension Service scientists and crop production experts in the land-grant university system for scientific and technical expertise.

The Department has provided high quality data to EPA in support of pesticide risk assessments. The goal of both EPA and USDA is to base regulatory decisions on the most accurate and robust risk assessments possible. Working with EPA, we have responded to the increased and changing needs for information by collecting and summarizing key pieces of real-world data.

My written testimony addresses in further detail a number of actions the Department has taken in response to the FQPA and to address the needs of agricultural producers, EPA and other stakeholders.

Thank you.

[The prepared statement of Hon. Rodney J. Brown follows:]

PREPARED STATEMENT OF RODNEY J. BROWN, DEPUTY UNDERSECRETARY FOR RESEARCH, EDUCATION AND ECONOMICS, U.S. DEPARTMENT OF AGRICULTURE

THE OFFICE OF PEST MANAGEMENT POLICY

The Office of Pest Management Policy (OPMP) was created in September of 1997 to help the Department respond to the demands of FQPA. OPMP has Department-wide responsibility and works across all USDA Agencies. The primary roles of OPMP are to coordinate and integrate USDA pest management-related programs and policies and to provide a central point of contact for EPA, growers, and other stakeholders. OPMP allows the Department to more quickly and efficiently respond to issues and needs arising from FQPA implementation. OPMP relies on Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES) scientists and crop production experts in the land-grant university system for scientific and technical expertise.

DATA

The Department has provided high quality data to EPA in support of pesticide risk assessments. The goal of both EPA and USDA is to base regulatory decisions on the most accurate and robust risk assessments possible. Working with EPA, we have responded to the increased and changing needs for information by collecting and summarizing key pieces of real-world data.

A critical piece of information in the assessment of human dietary risk is food consumption patterns and quantities. The Continuing Survey of Food Intake by Individuals (CSFII) conducted routinely by ARS to inform the Department's nutrition programs also provides EPA with statistically valid data for various age groups at the national level. Because the FQPA places special emphasis on ensuring adequate protection for children, USDA collected dietary consumption data on an additional 5,000 children. EPA used these data to substantially improve the confidence in children's dietary risk assessments. Working with EPA, USDA scientists also developed "recipes" that translate the food, as consumed and reported in the survey, into the basic agricultural commodities that make up the food. For example, the survey may report that a cheese pizza was consumed. The recipe translates the pizza into quantities of wheat flour, oil, tomatoes, onions, water, and milk as well as any other appropriate ingredients. The recipes mark the first time that such a detailed breakdown of foods is available to the public.

In determining the dietary exposure to pesticides, the other key piece of information needed is the amount of pesticide residue in or on food. When the daily consumption data are combined with the residue data, daily dietary exposures can be calculated. The Agricultural Marketing Service (AMS) began collecting pesticide residue data on fresh fruits and vegetables a decade ago and has successfully expanded the sampling program to include canned and frozen foods, grains, milk, meat, poultry, and, most recently, drinking water. The program is called the Pesticide Data Program (PDP) and for most commodities, samples are taken as close to the consumer as possible while still preserving the ability to identify the source. Both imported and domestic foods are tested using extremely sensitive analytical methods. PDP data are not available for all food-pesticide combinations. Where PDP data are not yet available, EPA must rely on estimates of exposure that frequently far exceed those measured at the consumer level. Use of PDP data provides a realistic estimate of consumer exposure to pesticide residues and results in a high level of confidence in the accuracy of EPA's dietary exposure assessment.

The National Agricultural Statistics Service (NASS) collects data on the pesticides used on a variety of crops. Data are collected directly from a sample of farmers and include information on the frequency, rate, and amount of pesticides used. The surveys are designed to collect statistically valid data at the state level. NASS data are used in the risk assessment process and also provide valuable information concerning the relative benefits or importance of a particular pesticide in crop production.

The Department (USDA) is working with EPA, the Geological Survey (USGS), and pesticide manufacturers to develop better tools for estimating the potential for pesticides to contaminate surface waters. This is being done to assess levels that may be found in drinking water—a requirement in estimating the aggregate risk a pesticide may pose to humans under the FQPA. Pesticide use data are essential inputs into the current efforts to develop a predictive regression model for surface water contamination by pesticides.

USDA has also made basic agronomic and pest management data available to EPA and all stakeholders. Working with our land-grant partners, interested agricultural producers, and independent crop consultants, the Cooperative State Research,

Education, and Extension Service (CSREES) and OPMP have funded and coordinated the development and publication of nearly 500 "crop profiles" that detail basic production and pest management information. The crop profiles are available on the Internet and provide information that supports risk assessment activities as well as the development of risk mitigation strategies. Crop Profiles provide realistic patterns of pesticide use rather than worst-case scenarios.

Building on the baseline information in the Crop Profiles, commodity groups and land-grant university specialists are developing Pest Management Strategic Plans to set priorities and guide research and new product registration activities. Sometimes referred to as Transition Strategies, these plans look to the future of pest management needs for the commodity and production region. The plans identify research, registration, education, and implementation priorities required to change pest management strategies in response to regulatory or consumer demands.

NEW RESEARCH PROGRAMS

Working with Congress, we developed and secured funding for three new pest management research programs in FY-1999. These programs work in concert with the already established Pest Management Alternatives Program (PMAP) ($1.6 Million in FY-02) that focuses on short-term alternative pest management tools.

The Crops at Risk program (CAR) ($1.5 Million in FY 02) provides competitive research funding for pest management alternatives in crops made vulnerable by FQPA implementation. The focus is on intermediate-term solutions to major pest management problems.

The Risk Avoidance and Mitigation Program (RAMP) ($4.9 Million in FY-02) focuses on long term competitive research funding for overall crop and pest management systems.

The Organic Transition Program ($1.5 Million in FY-02) provides funding for development of pest management strategies that help interested growers move from traditional production practices to organic agriculture.

INVOLVEMENT OF THE AGRICULTURAL COMMUNITY

Since passage of the FQPA, USDA has sought ways to inform and involve the agricultural community in implementation. EPA has been equally concerned about involvement of agricultural producers and has worked with us to develop transparent processes that encourage participation by all stakeholders.

One very successful mechanism has been the use of external advisory committees. EPA originally chartered the Tolerance Reassessment Advisory Committee (TRAC) in 1998 and subsequently rechartered it as the Committee to Advise on Reassessment and Transition (CARAT). The Deputy Secretary of USDA co-chairs the committee with the EPA Deputy Administrator.

Working with EPA and the agricultural community, USDA ensures that grower interests are represented in all pesticide regulatory decisions. OPMP conducts meetings and conference calls on specific chemical re-registration decisions. Using these mechanisms, agricultural producers have the opportunity to address risk assessment issues, crop production practices, and help develop workable risk reduction strategies.

Pest management experts associated with the land-grant universities work through the four recently created Regional Pest Management Centers in order to more efficiently and effectively address scientific research, regulatory, and implementation issues. Pest management experts have used the Regional Pest Management Center concept and structure to improve the exchange of information, achieve greater cooperation and improve stakeholder involvement.

REGISTRATION OF ALTERNATIVE PRODUCTS

USDA's Inter-Regional Project Number 4 (IR-4) program is supported by both CSREES and ARS and remains the principal means by which products are registered for minor uses. Generally, minor uses are specific uses in small markets where registration costs exceed potential returns to pesticide manufacturers. In these cases, the IR-4 program provides the expertise and much of the funding required to conduct field trials and prepare registration packages. Without adequate pest control measures, farmers would find it impossible to produce economically viable crops of fruits and vegetables that are absolutely critical to good nutrition and health. Loss of production could also seriously impact local farm economies and food processing interests. Pesticide manufacturers still bear the large costs of health and environmental testing required for initial registration of new active ingredients, but the IR-4 Program helps to ensure that many fruit and vegetable crops have access to these new production tools. Over the last several years, IR-4 registrations have

accounted for the majority of EPA's new crop registration decisions. EPA works closely with the IR-4 program to build increased efficiency into the minor crop registration program. Since passage of the FQPA, IR-4 has aggressively pursued the registration of new and safer pest management technology.

While I believe that USDA has made significant progress and contributed appreciably to the implementation of FQPA, I also recognize that there are a number of issues that demand further attention.

Regulatory and research programs operate on very different time lines and we need to find ways to improve our ability to keep pace with rapidly changing research and data collection needs. The CAR and RAMP programs mentioned earlier have been successful in responding to these changing needs. The Pest Management Strategic Plans, also mentioned earlier, are powerful tools that assist in anticipating research needs and we are making greater use of these planning tools in establishing the research agenda.

In some cases, implementation of alternative pest management technologies and strategies has been slow. New technology frequently demands education and training and often requires more information and more management time. Agriculture is subject to an almost endless array of variability in weather, pest, and economic cycles. Alternative methods must be proven to work consistently outside of the confines of closely monitored trials and small-scale demonstrations. Regulation and consumer demand are driving agricultural producers to change production technologies but we also need to look for ways to provide growers greater incentive to adopt newer and safer pest management systems.

Demands for pesticide use and residue data are usually far greater than our ability to supply them and we must carefully adjust priorities. In both of these areas, USDA will continue to work closely with EPA and USGS to better anticipate and plan for future data needs.

Some of the most promising pest management research involves biotechnology, but the lack of consumer acceptance, especially in export markets, has slowed the development and adoption of innovative solutions to many pest problems. Building consumer confidence in our research and all federal regulatory programs is essential to the ultimate acceptance of biotechnology and our ability to bring a new generation of pest management strategies on-line.

The Food Quality Protection Act of 1996 changed the standards for pesticide safety and laid out a rigorous time line to complete the review of all existing food tolerances. I am pleased with the working relationship that we have established with the EPA and look forward to a continued partnership as we work through the remainder of FQPA implementation.

Mr. GILLMOR. Thank you very much, Dr. Brown, and your full statement will be a part of the record.

The representatives of the U.S. EPA have arrived and we would invite them to come forward to the witness table.

Adam Sharp is the Deputy Associate Administrator in the Office of Prevention Pesticides and Toxic Substances and he is joined by Lois Rossi, who is the Director of Pesticide Programs.

So we will turn it over to you for a brief statement.

STATEMENT OF HON. ADAM SHARP, DEPUTY ASSOCIATE ADMINISTRATOR, OFFICE OF PREVENTION PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. SHARP. Thank you, Congressman. I appreciate the invitation to be here today. It has been an interesting morning, but we made it. We have been on the road for a few hours, not expecting the snow. But I do appreciate the invitation to come here to this field hearing on the Food Quality Protection Act. I know it is the first official hearing on this law since it was passed in 1996.

A little bit about myself first. I am brand new at the EPA, just started not even 2 months ago, but it is nice that the first FQPA hearing is in Ohio, because this is where I am from, family farm in southeastern Ohio, raised on a dairy and livestock farm about

3 hours southeast of here; graduate of Ohio State University College of Agriculture and worked for the Farm Bureau for the last 7 years in Washington, DC as their pesticide specialist. So this issue is something that is very near and dear to my heart and I understand the needs of a lot of folks who will be testifying today on the topics we are going to discuss.

I am also pleased to be here with USDA. They have been a good partner as we have moved forward in FQPA implementation and then also I wanted to introduce Lois Rossi, Division Director for Special Review and New Registration at EPA. I am going to be relying on her for some expertise, being that I am still coming up to speed on some of the issues that we are dealing with. I welcome the opportunity to discuss this law and bring you up to date on the Agency's activities in implementing this important piece of legislation.

Let me first start of with what is FQPA. FQPA was developed based on a desire to establish a single food safety standard for both raw and processed food commodities. The new law reflected the desire of Congress to increase to protections regarding potential dietary risks from pesticides and to move the Federal food safety system ahead scientifically.

The new health based safety standard embodied in FQPA calls for a reasonable certainty of no harm standard. FQPA mandated that the Agency, as appropriate, utilize an extra tenfold margin of safety for special sensitive populations. The legislation also introduced new rigorous, scientific criteria, such as aggregate exposure, and new requirements to evaluate cumulative risk for exposure to multiple pesticides which share a common mechanism of toxicity, or cumulative risk assessment. I will talk more about that in a second.

Since enactment of FQPA, EPA has worked to implement the new requirements in a way that achieves the goals of reducing pesticide risks. We also need to recognize that it is essential that farmers continue to have the tools that they need to provide the American public with the safest, most abundant food supply. The Agency also followed several important principles in implementing the Food Quality Protection Act; namely, ensuring that we use sound science, that our actions are transparent and I think we have done an admirable job of that. We have extensively consulted with the public stakeholders and other Federal agencies, particularly with the U.S. Department of Agriculture, USDA, here to my right, and that our decisions also allow a reasonable transition for agriculture to adopt new pest management tools and techniques.

Some of the key accomplishments under FQPA. EPA has had many successes implementing the law. We have met deadlines established for the reassessment of pesticide tolerances, taken significant action to reduce risks when necessary and done so in a responsible manner. We have established greater communication with groups, stakeholders and others impacted by our decisions and improved our coordination with the U.S. Department of Agriculture on pesticide issues.

To that end, EPA and USDA have established the Committee to Advise on Reassessment and Transition, known as the CARAT Committee—sometimes a tongue twister—to strengthen the inter-

action with all stakeholders involved. The CARAT helps to ensure that our decisions are open, well understood and take into consideration the input from all stakeholder groups.

Some of the important milestones for FQPA implementation. Under the Food Quality Protection Act, EPA is required to reassess some 9700 existing tolerances to ensure that they meet new safety standards that were created under the FQPA. The Agency met the first statutory deadline that we had and we plan to meet the next one as well, this coming August. EPA, under the previous administration, also settled a lawsuit with the Natural Resources Defense Council, which also established some deadlines for reassessment. We have met the deadlines under that settlement as well and plan to continue to meet the deadlines established under that settlement. Sound science and the importance of protecting public health will continue to drive our decisions.

Cumulative risk. As I mentioned earlier, FQPA requires several advances in the science supporting the regulation of pesticides. Perhaps no area is more complex than assessing cumulative, risk, in which the Agency must consider the effects of multiple pesticides that act the same way in the human body.

Recently, these methods have been used to conduct a preliminary cumulative risk assessment for organophosphate pesticides which have been identified—this first class of OPs, as they are commonly referred to, will be the first cumulative risk assessment done and there was a common mode of action established for that group of pesticides. This preliminary assessment has recently been reviewed by independent scientists and released for public comment. We expect to incorporate the scientific recommendations, as appropriate, and publish an updated cumulative risk assessment for the organophosphates this coming spring. This cumulative assessment is expected to be completed by August of this year.

Identifying potential non-contributors. This is an issue that got some discussion in the last CARAT advisory committee just a couple of weeks ago. Currently, EPA is exploring the concept of whether there are tolerances that could be reassessed prior to August because they are not know to make any negligible contribution to cumulative risk. The Agency is currently developing a Federal Register notice expected to be published this spring—actually in the next week or 2—that discusses the general criteria in identifying non-contributors for chemical/crop combinations.

Some of the principles for FQPA implementation that we have evolved. Through all these activities, we have worked hard to open up our processes for making decisions and have allowed for public comment on preliminary decisions so that they may have—so that those who may be affected by those decisions have the opportunity to share relevant information and real experiences. We have sought input from the public and the agencies, such as the Department of Health and Human Services and USDA, to bring differing perspectives and expertise to bear on our decisions. EPA is also working hard with USDA to address the challenges of transition. It is important that EPA and USDA focus our efforts on developing a seamless and coordinated approach to ensuring growers and others have the necessary pesticide tools in the future.

Conclusion—a couple of high points—it is our pleasure to be here again today with USDA. Decisions on pesticides must be made within a full partnership between the Department and the Agency. We recognize the very real impacts that our decisions can have on people who make their living through agriculture and USDA and others,a nd we understand that USDA plays a vital role in coordinating our efforts with farmers and pesticide users. I look forward to strengthening that effort within the Agency.

EPA recognizes that it is important for us to have a full and open dialog with all stakeholders. The Agency is listening carefully to the concerns of everyone as we proceed with FQPA. We have held numerous stakeholder meetings and numerous conference calls and advisory group meetings to seek that input. There has been an overwhelming response I think by commodity groups and non-agricultural pesticide user groups to partake in a number of those types of sessions and meetings and conference calls. The Agency is listening to those comments. It is with these commitments, with everyone at the table, listening and learning, that we will successfully address the current and future challenges in implementing this very important law.

Thank you for the opportunity to comment here today. I appreciate and look forward to answering any questions you may have.

[The prepared statement of Hon. Adam Sharp follows:]

PREPARED STATEMENT OF ADAM SHARP, ASSOCIATE ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

INTRODUCTION

Thank you for the invitation to appear before you today. My name is Adam Sharp and I am the Associate Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances at the Environmental Protection Agency (EPA). While I have only been with the Agency for two months, I have worked on pesticide issues for some time. Certainly the most profound change in pesticide regulation has been the 1996 passage of the Food Quality Protection Act (FQPA). I welcome the opportunity to discuss this law and bring you up-to-date on the Agency's activities in implementing this important piece of legislation.

WHAT IS FQPA?

FQPA was developed based on a desire to establish a single food safety standard for both raw and processed food commodities, while also taking coverage of pesticide residues out of the scope of the so-called Delaney Clause. The new law reflected the desire of Congress to increase the protections, particularly for children, regarding potential dietary risks from pesticides, and to move the federal food safety system ahead scientifically.

The new health based safety standard embodied in FQPA calls for a reasonable certainty of no harm to human health. FQPA mandated that the Agency, as appropriate, utilize an extra ten-fold margin of safety for children. The legislation also introduced new rigorous, scientific criteria—such as aggregate exposure—to evaluate all possible routes of pesticide exposure together and new requirements to evaluate cumulative risk from exposure to multiple pesticides which share a common mechanism of toxicity.

When FQPA was passed, EPA had only limited experience with these new and groundbreaking scientific and regulatory requirements. FQPA significantly strengthened the safety standard for all pesticides used on food, and identified a set of complex scientific issues, which have taken years to address.

Since enactment of FQPA, EPA has worked to implement the new requirements in a way that achieves the goals of reducing pesticide risks, particularly for children, while recognizing that it is essential that farmers continue to have the tools they need to provide the American public with a safe and abundant food supply. The Agency has followed several important principles in implementing FQPA, namely

ensuring that we use sound science, that our actions are transparent, that we extensively consult with the public and other federal agencies, particularly with the U.S. Department of Agriculture (USDA), and that our decisions allow a reasonable transition for agriculture and for the important public health uses of pesticides, to adopt new pest management tools and techniques.

KEY FQPA ACCOMPLISHMENTS

EPA has had many successes in implementing FQPA. We have met deadlines established for the reassessment of pesticide tolerances (legal residue limits), taken significant actions to reduce pesticide risks in a reasoned and responsible manner, established greater communication with groups impacted by our decisions, and improved our coordination with the USDA on pesticide issues. To that end, EPA and USDA have established the Committee to Advise on Reassessment and Transition (CARAT) to strengthen the interaction with all our stakeholders. CARAT helps to ensure that our decisions are open, well understood, and take into consideration the input from all interested parties. In addition, EPA Administrator Christine Todd Whitman created a position on her immediate staff for a Senior Agricultural Advisor and appointed Jean Marie Peltier, who previously worked closely with California agriculture and was an experienced state regulator.

Despite the additional requirements imposed by FQPA, EPA has been able to maintain its pre-FQPA productivity in registering new pesticides and reduce the response time for emergency exemption requests. Working with USDA, we have significantly improved the data used to make decisions on the registration and reregistration of pesticides. We have also taken steps to make our reviews, and the science supporting them, more transparent for growers and the public. While it has been five and a half years since FQPA took effect, we have seen an increase in the registration of reduced-risk pesticides and risk mitigation for some existing pesticides.

IMPORTANT MILESTONES IN FQPA IMPLEMENTATION

Under FQPA, EPA is required to reassess some 9,700 existing tolerances to ensure that they meet the new safety standard. The Agency was given statutory deadlines for accomplishing these reassessments, the first of which was to reassess 33 percent of the existing tolerances by August 3, 1999. We met that goal, and anticipate meeting the next statutory goal, which is to reassess an additional 3,208 tolerances, or 33 percent, by August 3 of this year. EPA also settled a lawsuit by the Natural Resources Defense Council (NRDC), concerning the progress of reassessment and the priority we were giving to evaluating certain pesticides. We have met all the deadlines required by that settlement to date, and we fully expect to continue to meet the future deadlines. Throughout tolerance reassessment and compliance with the NRDC deadlines, it is important to note that our decisions will continue to be fully supported by sound science and extensive stakeholder involvement. Sound science and the importance of protecting public health will continue to drive our decisions.

CUMULATIVE RISK

As I mentioned earlier, FQPA requires several advances in the science supporting the regulation of pesticides. Perhaps no area is more complex than assessing cumulative risk, in which the Agency must consider concurrently the effects of multiple pesticides that act the same way in the human body. The concept of cumulative risk has been discussed by scientists for years, but FQPA required the Agency to actually apply it on an ongoing basis for specific pesticides which share a common mechanism of toxicity. After years of scientific work, the Agency has now developed a preliminary framework for conducting cumulative risk assessments. These new tools and methods were developed in consultation with independent scientific groups.

Recently, these methods have been used to conduct a preliminary cumulative risk assessment for organo-phosphate insecticides, which have been identified as one of the pesticide classes which share a common mode of toxicity. This preliminary assessment has recently been reviewed by independent scientists and released for public comment. We expect to incorporate the scientific recommendations, as appropriate, and publish an updated cumulative risk assessment for the organophosphates this Spring. This cumulative assessment is expected to be completed by the August 3 deadline.

IDENTIFYING POTENTIAL NON-CONTRIBUTORS

Currently, EPA is exploring the concept of whether there are tolerances that could be reassessed prior to August because they are known to make, at most, no more than a negligible contribution to cumulative risk. The Agency is currently developing a Federal Register notice that discusses the general criteria used in identifying non-contributors for chemical/crop combinations. We expect this notice to be published this Spring for public comment.

FQPA IMPLEMENTATION PRINCIPLES

Through all of these activities, we have kept our implementation principles firmly in mind. We have applied the most stringent and exacting scientific standards to ensure that we take only those actions that are necessary and effective. We have worked hard to open up our processes for making decisions, and have allowed for public comment on preliminary decisions, so that those who may be affected have the opportunity to share relevant information and real experiences. We have sought input from the public and agencies, such as the Department of Health and Human Services and USDA, to bring differing perspectives and expertise to bear on our decisions. EPA is also working hard with USDA to address the challenges of transition. It is important that EPA and USDA focus our efforts to develop a seamless and coordinated approach to ensure growers have the necessary pest control tools. I would also like to acknowledge the roles that states have played in reaching the agricultural community and in carrying out the decisions under FQPA.

CONCLUSION

It is a pleasure to be here today with USDA. Decisions on pesticides must be made within a full partnership between USDA and EPA. We recognize the very real impacts that our decisions can have on people who make their living through agriculture and USDA has played a vital role in coordinating our efforts with farmers and other pesticide users. Our decisions must fully protect public health and the environment, while being sensitive to the needs of agriculture.

EPA recognizes that it is important for us to have a full and open dialogue with all stakeholders. The Agency is listening carefully to the concerns of everyone as we proceed with FQPA. It is with these commitments, with everyone at the table, listening and learning, that we will successfully address the current and future challenges in implementing this important law.

Thank you for the opportunity to appear before you today. I will be pleased to answer any questions that you may have.

Mr. GILLMOR. Thank you, Mr. Sharp. Did you have an additional statement, Ms. Rossi?

Ms. ROSSI. No, sir.

Mr. GILLMOR. Okay.

If I might start by asking you some questions, Dr. Brown. Could you explain more fully the differing roles that EPA and USDA play in reassessing pesticides and could you describe how you think that relationship is working?

Mr. BROWN. Certainly. First of all, as I mentioned before, EPA has the major direct responsibility and I believe the major challenge in this process.

On the other hand, USDA, first of all feels a great responsibility to provide correct scientific data to EPA for their purposes, at their request. Also, as we see areas that we within USDA feel need more data, better data, different kinds of data and so on, we are working to provide that information.

Second, as the risk assessments are prepared, USDA works with the producers to review those risk assessments. There is a challenge there that we face constantly in that these risk assessments come after much work and much preparation and usually with a rather short time line for review.

Finally, in the implementation area, the USDA is involved with the producers, through the land-grant universities and others who work with producers directly to implement these new programs.

Mr. GILLMOR. Is USDA, in your view, a full partner with EPA in reviewing and approving the tolerance reassessments?

Mr. BROWN. I believe that USDA is without a doubt a full partner with EPA in this process.

Mr. GILLMOR. What is the size of USDA's staff that is dedicated to Food Quality Protection Act process and in your view are more staff and resources needed to allow the Department to interact more fully with EPA as it plows ahead to meet the statutory guidelines, and also the deadline set by the NRDC lawsuit?

Mr. BROWN. We have 12 people assigned to the office directly. But, I should point out here that budget-wise, which is the easiest way for me right now to report USDA's contribution, in 2001, USDA devoted $88 million to Food Quality Protection Act related activities. There was $92.5 million in 2002 and again in the 2003 budget.

We clearly would like to have more resources, especially in the area of risk assessment. We are doing our best to keep up with the data requirements as they come through.

Mr. GILLMOR. Do you think that the NRDC lawsuit and the tighter timeframes that have been imposed on EPA have hindered USDA's ability to be involved in the Food Quality Protection Act tolerance review process?

Mr. BROWN. Shorter time certainly makes it harder to keep up. The challenge here is that we are dealing with practices used in agriculture that have developed over 100 years, however many years you want to go back, and we are trying to find new ways, replacements and so on in a very, very short time. When that time is shortened even further, of course, it makes it much more difficult to keep up.

Mr. GILLMOR. Let me go to Mr. Sharp and Ms. Rossi, either one of you may feel free to answer.

Conducting improved risk assessments of the high priority pesticides is at the heart of the FQPA process, and although many of EPA's reassessment decisions have been accomplished by clearing away the underbrush approach in the form of voluntary cancellations of outdated tolerances, under FQPA, EPA is conducting some of the most complex and laborious risk assessments it has ever undertaken and those assessments combine theoretical modeling with available data to estimate the likely health and safety risks presented by those chemicals. So the question is what is the state of the science for these aggregate and cumulative exposure modeling procedures?

Mr. SHARP. There has been extensive science policy development on behalf of the Agency. Over 20 different science policy areas have been identified within work groups such as the CARAT work group, starting 6 years ago—actually starting pretty much when the law passed.

So initially there was a lot of identifying of where the science needed to be developed and what needed to be flushed out, what kind of data was needed. And this began 6 years ago. In the meantime, there has been over 20 of these different science policies that

have been identified, all of them have been put out for public comment by the Agency and there has been 23 different science advisory panel meetings held. And the science advisory panel of course is an independent body of scientists that review the work of the Agency and we have taken various pieces of the FQPA science policies to that panel 23 times—6 times just for the cumulative risk assessment directly. For aggregate, I believe at least once or twice, as well as also public comments on those policies as a whole and/or in part as well.

The cumulative policy, the last portion of it had gone to the science advisory panel just not long ago actually. It was—the preliminary cumulative risk assessment was sent to the SAP to review about a month ago and they actually just gave us back their science advisory panel report on the cumulative assessment not even a week ago. So we are right now reviewing the assessment on it.

So there has been a thorough vetting of the science policies involved in FQPA, because as you said, they are incredibly complex and incredibly confusing. But there has been a tremendous amount of input given by industry, environmental groups, agriculture and others as well, into that process.

Mr. GILLMOR. As I understand it, assessing risk is a function of assessing toxicity and exposure; and that is, risk is not just measured by how toxic a substance may be, but it is also necessary to assess the potential for exposure to that substance in order to determine whether it presents a risk.

Now with regard to FQPA, you believe that the exposure of children to organophosphates in the form of residues on fruits and vegetables is properly being estimated by EPA and is there any reason to think that exposure of children is being either substantially under- or over-estimated under the FQPA process?

Mr. SHARP. I think it is being pretty adequately assessed when you are looking at exposures. There are various portions of data that are used to look at the exposure of various groups of populations, age groups primarily, and the Agency actually looks at data by different age groups, children being one of those age groups that is considered when looking at risk and looking at exposure.

So, no, I think actually as far as the law being implemented, as far as the actions being taken, the assessments that are being conducted are fair, they are not under- or necessarily overly assumed.

Mr. GILLMOR. Thank you. Dr. Brown, do you agree basically with Mr. Sharp's assessment?

Mr. BROWN. Yes, in principle I do. We have a couple of concerns. One is again with the need to deliver data quickly and the quantity and quality of data that needs to be provided. One instance in particular is in the data on consumption provided by the Agricultural Research Service. When that data was collected, it included a warning against use of this data for statistical purposes. We would feel more comfortable if we had more complete and better data, and I am sure EPA would agree.

Mr. GILLMOR. And Mr. Sharp is indicating he agrees with that.

Dr. Brown, a risk assessment is only as good as its data and FQPA requires EPA to consider more data for tolerance reassessment than it ever has in the past. And as a result, EPA's risk as-

sessment employs data sets of varying scope, varying quality, and while some of the data are provided by manufacturers, other data are provide by Federal agencies, including USDA. Can you describe the types of dietary exposure data USDA is contributing to the Food Quality Protection Act implementation, and in your view—well, let us just leave it at that.

Mr. BROWN. Yes, the primary data with regard to consumption is a continuing survey of food intake by individuals. This is conducted routinely by the Agricultural Research Service nutrition programs, which provides data to EPA linked to various age groups. This is especially important as we look at the needs of infants and children.

Because the FQPA has special emphasis in these areas, we added 5,000 children to the data survey last time it was done, to improve the quality of the data there. Determining dietary exposure to pesticides is very difficult without increasingly large surveys to improve the data. We have improved—we are closer, we do not think we are as close as we would like to be.

Mr. GILLMOR. Thank you very much.

Mr. Sharp, as I understand it, EPA's computer model for cumulative exposure does not allow for identification of risk drivers, meaning uses that are significantly contributing to exposure resulting in unacceptable levels of cumulative risk. Has EPA identified any risk drivers so far in its draft cumulative risk assessment of organophosphates? And if not, when will the Agency be able to do so?

Mr. SHARP. Actually the model, you can find drivers, but it is a highly process and maybe more time consuming than need be. But there are a couple of other models being developed, one by industry and then another one that is being developed by a private group. The idea right now is that the model I believe that is being developed by industry is going to be sent to a science advisory panel to review as well here in about a month. And they are going to look at the accuracy and the model development there.

And then what we are going to do is we are going to look at comparing the model that the Agency has compared to these other couple of models and basically do some truth testing and see what each one of these models are saying and what they are predicting, and at that time, we will be able to determine if there are certain areas that are showing more of a driver for risk than others. Right now we have not done that yet. So directly to that part of your question, we do not—have not yet and have not run a run to find out what those risk drivers may be to date. But we will certainly be doing that and we will be doing that this spring actually.

The idea is that we have until—we have until the end of May, is what we have set ourselves as our own deadline on recommendations from the public to release a preliminary or a refined risk assessment of the cumulative group of OPs. So that is our goal right now, is to put out a revised version of that by the end of May or the first week in June and we committed that publicly a couple of weeks ago. And at that time, this question will be further down the road and we will be able to answer it better and talk more about the drivers as well as the other models in some of the comparing that we are going to do before we release a final product.

Mr. GILLMOR. Thank you very much.

Mr. SHARP. Thank you.

Mr. GILLMOR. Dr. Brown, Food Quality Protection Act implementation has a substantial economic impact on the agricultural sector, and ultimately, based on the risk assessment and other statutory factors, EPA must decide whether to revise or revoke existing tolerances and exemptions, require changes in how pesticides are labeled and otherwise restrict or reduce the use of certain pesticides on food.

Those pesticide manufacturers and users must anticipate those changes and begin to evaluate their options including the development of substitute products. Can you describe the range of mitigation steps that you expect farmers to be faced with once the cumulative exposure assessment of OPs is completed?

Mr. BROWN. I would like to comment on that. First of all, there are a range of challenges to producers, depending on what they are producing. One of the biggest challenges is in the crops that are sometimes referred to as minor crops. If you look at the cash value of the crops produced in the United States, the minor crops are right around half, so I think minor may not be the right word. But there are pesticides and treatments used on these crops which are used in small enough quantities that it is not economically feasible for the producers to go through the recertification process. In that case, a program called IR-4 has been used. This is a joint program with USDA and EPA and the producers and so on, which is being used to help with some of these low volume products. The IR-4 program has been able to in fact, on a numbers basis, account for the majority thus far of the reregistrations.

If we have time to prepare, we can have strategic plans for various crop uses and ways to help through the county agents and the commercial crop specialists and all the other people involved to help producers switch over. We cannot always switch over and meet the new requirements at the same cost, which is a great concern, as we are more and more involved in world trade and we are more and more concerned about regulations that affect American producers differently than they affect international producers.

Mr. GILLMOR. Let me direct a question both to you, Dr. Brown, and also to you, Mr. Sharp. In your view, are the issues relating to FQPA, which are raised by land-grant universities and grower groups that your Department interacts with routinely being adequately heard in Washington and being properly addressed in the Food Quality Protection Act process, and is the assessment process, review process, CARAT process, working effectively in your view? And what additional improvements would you identify and recommend?

Mr. BROWN. I believe beyond the day-to-day work of collecting data and going through all the work that EPA has to do in each case, the input from the growers, from the land-grant universities and so on, is essential to make sure we do the right things; and I should add that we do the most important things first.

We have established four regional pest management centers which are serving a great need in this area to help us go ahead with this work.

Mr. SHARP. Starting off with the CARAT, the CARAT is, of course, a transition advisory group from the TRAC and the TRAC that was established right after FQPA was passed and it has about 40-50 members on it from all different stakeholder groups, including USDA/EPA representation as well as CDC and some other folks who have sat on it at various times. And also at those meetings—and I think I have been to every single one of them and there have been a number of them that have been very productive—really a lot of the concerns that I think initially were being heard on FQPA were addressed within CARAT to a degree of process, and there was a lot of questions about what is the process that EPA does to assess risks of pesticides.

As those questions became clear, this advisory group helped advise the Agency and the Department on how to come up with a process that everybody understood and everybody had an ability to have input into. And through that process, we developed the six-step FQPA risk assessment process. It is very clear, products move from step one to step six and there is input at various times to the public. So that has been, I think, one of the major achievements of CARAT. So that is one part of this.

The identification of science policy, as I mentioned earlier, has been another very key part of the CARAT that has helped the Agency and the Department focus on how to do this risk assessment under the Food Quality Protection Act.

So there has been several things that the CARAT has been instrumental on, incredibly key things. And that has come from the input of all the stakeholder groups. So the CARAT has been successful. We plan on continuing the CARAT and we are actually going to have another work group meeting of the CARAT here in a couple of months when we have released this draft of the cumulative risk assessment. So that in partial has brought in some of the grower groups' and stakeholders' concerns.

I also mentioned that as we move through the six step process, EPA has more than several staff who help us identify, in working with USDA, identify users and those who are the folks who are on the ground using these products, and those who understand how they are used and are bringing them into the process. So we have a formal comment period on individual risk assessments, which was also something that I think came out of input from the CARAT and the TRAC, that allows people to formally file comments into the process on individual risk assessment and also give or provide information to the Agency. In addition to that, we then hold follow up conference calls for individual products and then we hold a final closure call on individual products before a risk assessment decision is made, so we have a lot of opportunities to have the stakeholders involved, particularly farmers and growers and folks who know how to use the products. So those have been incredibly helpful. I think since the FQPA has been passed in 1996 until now, you have seen an incredible increase in the quality of the risk assessments that are being produced because of that input.

Mr. GILLMOR. Well, thank you very much. We will wrap up this first panel, but your full statements are part of the record and anything else that you want to submit.

Also before we break with this panel, I would ask if there is any brief comment that you care to make in summary. If you do, feel free.

Mr. BROWN. From USDA's point of view, again, we appreciate the working relationship which has developed and continues to develop with EPA. We have some concern that, first of all, as this process started, many of the fears that we and others had have been resolved by continually working together, but we do have a concern that science to do the job is being developed along with the policies. There is some concern now, I know EPA has the same concerns, and there are crops out there, many of them we continue to hear about, that we are worried about the impact on things such as apples, peaches, grapes, tomatoes, especially in the area of cumulative risk. We are going to have to figure out how to deal with that.

Another one that has come up that is a great concern is a chemical used in the storage of small grains, especially in smaller storage areas where we seem to have no alternative and we have a long way yet to work through that.

We appreciate the time to be here.

Mr. SHARP. Thank you. I have worked with USDA on FQPA issues for years and it is a tough law to deal with as far as scientific standards and developing this process. The Agency and the Department have come a long way and I think we still have a long way to go though. There are a number of challenges that we do face in developing science policies, we are getting there and with the help of the science advisory panel, stakeholders and others, the information is ever increasingly good.

I am looking forward to strengthening our ties with USDA in this process because I really do think that the information that they provide, especially PDP data, is terrific stuff that is used. It gives a good accurate portrayal of what really is happening out there as far as exposure to the public.

Cumulative risk assessment—and Dr. Brown touched on cumulative risk assessment—a little bit about kind of where we are, to wrap up on things. We had 9700 tolerances that EPA is to reassess over a 10-year timeframe. We have finished about 4,000 of those. The goal or the next statutory deadline that is required by Congress is 6,400 products to be finished by this coming August. We hope to actually get beyond that and have more like about 7,000 completed by August. So we think we are well on our way to meeting the statutory goals.

Also, as fare as the NRDC settlement, they are releasing a revised cumulative risk assessment. We do plan to meet that goal as well and to have that revised policy released before August, possibly as early, as I mentioned, by early May. So we may meet that deadline actually early.

Strengthening our ties in some of the other areas with HHS and other groups, CDC, who are also involved is something else that we need to work on more. USDA has been a great partner at the table in CARAT and others, and we look forward to strengthening the ties with some of these other branches of government, who have had key input on certain areas and on certain products, but we would like to do more.

So there are certainly some challenges left and we look forward to working on those with the Department and others.

So thank you for having us out today, I appreciate it.

Mr. GILLMOR. Well, thank you both for your input.

We will take about a 1-minute break so that the second panel can come forward.

[Brief recess.]

Mr. GILLMOR. In addition to the witnesses we will be hearing from this morning, we have had a number of groups who have asked to submit testimony—Improving Kids' Environment from Indianapolis, the Implementation Working Group, CropLife America and The American Nursery and Landscaping Association. And without objection, these will be included in the committee record and the subcommittee will also keep the record open for a 10-day period to receive additional statements.

Our panel this morning is Mr. Terry McClure, who is President of the Ohio Farm Bureau Federation; Christiane Schmenk, who is the Director of the Environmental Stewardship Team of The Scotts Company representing CropLife America; Robert Marquette, who is President of Ram Exterminating on behalf of the Ohio Pest Control Association; and Mr. Jeffrey Zellers, a farmer, who is President of K.W. Zellers & Son of Hartville, Ohio. And one witness who was scheduled to be here, Jane Forrest Redfern, representing Ohio Citizen Action, called this morning, she is from Dayton, and said she would not be here because of the weather.

Always deferring to presidents, we will go to Mr. McClure first.

STATEMENTS OF TERRY McCLURE, PRESIDENT, OHIO FARM BUREAU FEDERATION; CHRISTIANE W. SCHMENK, DIRECTOR, ENVIRONMENTAL STEWARDSHIP TEAM, THE SCOTTS COMPANY; ROBERT MARQUETTE, PRESIDENT, RAM EXTERMINATING ON BEHALF OF THE OHIO PEST CONTROL ASSOCIATION; AND JEFFREY ZELLERS, PRESIDENT, K.W. ZELLERS & SON

Mr. MCCLURE. Thank you, Mr. Chairman, and thank you for bringing this hearing here to our District, we appreciate that.

My name is Terry McClure, I am a partner with my family in McClure Farms in Grover Hill, Ohio, located in Paulding County. I also currently serve as the President of the Ohio Farm Bureau Federation, the state's largest farm organization. Our family raises corn, soybeans and wheat on 2700 acres. As a responsible user of crop production products, I depend upon those tools to control week and pest problems and provide the world and U.S. consumer with a safe, nutritious, affordable food supply.

I thank Chairman Gillmor and the subcommittee for the opportunity to share my concerns regarding the implementation of the Food Quality Protection Act of 1996. I also have the privilege of sharing with you a letter containing perspective of 13 county Farm Bureau presidents in Representative Gillmor's district and ask to have it included in the record.

Mr. GILLMOR. I had the opportunity to meet with the Farm Bureau presidents about a week ago, so we are happy to hear from them.

Mr. MCCLURE. Thank you.

A $73 billion component of the state's economy, agriculture is important to Ohio's continued viability. Here in Representative Gillmor's district, agriculture accounts for $6.6 billion in economic output and employs nearly 81,000 Ohioans. Although we have a unique agriculture in Ohio with livestock, grains and oilseeds product alongside a wide variety of fruits and vegetables, virtually all of Ohio agriculture is, in some form or another, dependent on crop protection products for its success, and will be affected by the decisions EPA makes in determining the process by which these important tools will be reviewed.

As FQPA implementation moves forward, our concern lies in the fact that OPs are just the first pesticide class to be subject to review and reassessment. As other pesticide classes are reviewed, the reassessment will be approached in much the same manner and adhere to the same policies currently under development. This is not a concern about a few minor uses of pesticides, but rather the use of one of U.S. agriculture's main production tools is at issue.

How FQPA affects farming operations—the agricultural industry in Ohio and the United States is experiencing intense economic pressure and competition from agricultural producers throughout the globe. Our competitors are found in the next county or State and Federal regulations impacted us all equally. However, Argentina and Brazilian farmers vying for our domestic and international customers, we cannot afford to hand them the competitive advantage of restricting our production tools while importing their corn and soybeans produced with these very same tools.

On our farm, we primarily raise corn and soybeans. Without herbicide application, we would experience at least a 50 percent decline in our corn yields, costing well over $7,000 on a 100-acre corn field. Further detracting from the value of the corn is the high weed seed content and the declining quality, both of which would result in a reduction of price.

To control weeds and produce a high quality crop, we use Atrazine, an effective, affordable, broadleaf herbicide. Very few other products are available that do not contain this effective product and those that do, often recommend their use in tandem with this affordable product. One product, Balance Pro, is much more expensive to use, compared with the $3 per acre cost of Atrazine. Balance Pro cost me well over $10 per acre, an increase of $7 per acre in input cost.

A loss of insecticides would also impact my ability to control the development of pest resistance. Warrior, one of our more important broad spectrum, post-emergency products, is used to control a variety of pests, including armyworm, earworm, aphids, cutworms and others. To achieve the same control, I would need to apply a combination of pesticides, increasing my cost by $.00 to $7 per acre in product alone. Added to that cost, the additional expense of multiple applications. One product that would be a part of the combination is Capture, an insecticide that must be applied to the soil at planting time. This product must be applied before I can determine whether there is an insect problem. Warrior is applied only after evidence of insect damage appears.

As you can see, when these broad spectrum, ineffective, inexpensive tools are taken away from Ohio and U.S. farmers, it costs sig-

nificantly more to produce crops. Use of these same tools by growers in other countries place domestic farmers at a disadvantage and make it more difficult to compete in the global market.

If we are importing food produced using the very tools eliminated for U.S. use due to safety concerns, are we really protecting our consumers?

Process challenges. I am not a scientist and leave others to explain the very real concerns we have with the faulty methodologies currently promoted by EPA. I, however, have trouble understanding why EPA is advocating regulating pesticides at the 99.9 percentile when it means going to extreme effort to protect individuals who consume eight pounds of grapes per day or two quarts of apple juice and two quarts of pear juice a day. Further, these are very unlucky people who just happen to select grapes and juice that have the maximum residue allowed on those products. To compound the problem, this data cannot even be corroborated.

The lack of transparency on how decisions are being made at EPA, as it conducts product reviews is a grave concern to agricultural producers. Too often decisions are made before the process is approved on how the decisions are determined and there is very little opportunity for interested stakeholders such as myself to participate. As much as we would like to be, farmers and the public are not typically comfortable just trusting that everything will be resolved satisfactorily.

We believe that if common sense and sound data and methods are employed, there will be very few, if any, losses. However, in the event that uses are lost, there is currently no strategy in place for how EPA will decide which products and uses will be eliminated. The policy dictating how this risk mitigation will be conducted should have been determined before the first use was canceled. It was not and this process still has not been identified.

My final concern with the FQPA implementation process involves how EPA anticipates transition will occur when and if cancellation and restriction decisions are made. In addition to a lack of strategy on how to address the transition, there are few, if any, products to which agricultural producers can switch. With its focus on FQPA implementation, EPA has flowed registration of new products, thereby limiting farmer access to new alternatives. Further, these alternatives must be economically feasible. Trading off an effective, affordable crop protection product for a more expensive pesticide that does not offer the same level of protection is not realistic for continued competitiveness of U.S. and Ohio agriculture.

For a proposed solution, we ask the EPA to employ common sense in its approach to FQPA. A reasonable approach to the implementation of FQPA should result in a workable outcome with few adverse impacts. We must have a balanced, transparent implementation of the FQPA, based on real data and not theoretical risk, including workable strategies on risk mitigation and transition implementation. The availability of affordable, effective alternatives should be considered when uses are canceled, including cancellations arrived at through registrant negotiation.

We ask Congress to increase funding for USDA's Office of Pesticide Management Programs and other FQPA activities. As a full partner in the implementation of this law, USDA has been unusu-

ally quiet on the issue, due to the lack of focus and of funds. We depend upon USDA to communicate how crop protection products are used, how food products are handled and to track residue levels on domestic and imported food. This communication is not happening.

I ask for some analysis of how it is affecting the marketplace and our ability to compete in both the domestic and international markets. It must be determined if FQPA is resulting in unintended consequences such as an increase in imports, a competitive disadvantage with our international customers, and ultimately economic failures of U.S. farmers without intended benefit of enhanced food safety.

I appreciate the attention of the Subcommittee on Environment and Hazardous Materials and ask for your continued consideration. Congressional involvement and oversight is needed to ensure that EPA's decisions are reasonable, well supported by reliable information and balanced as intended by Congress when FQPA was passed. We cannot afford to further disadvantage U.S. and Ohio farmers and turn over food production to the rest of the world as a result of the lack of sound science in our regulatory actions.

Thank you for the opportunity to address you and I look forward to answering any questions. Thank you.

[The prepared statement of Terry McClure follows:]

PREPARED STATEMENT OF TERRY MCCLURE, AGRICULTURAL PRODUCER

Mr. Chairman and members of the Committee, my name is Terry McClure, a partner with my family in McClure Farms in Grover Hill, Ohio located in Paulding County. I also currently serve as President of the Ohio Farm Bureau Federation, the state's largest farm organization. Our family farm raises corn, soybeans and wheat on 2,700 acres. As a responsible user of these products, I depend upon these tools to control weed and pest problems and provide the world and U.S. consumer with a safe, nutritious, affordable food supply.

I thank Chairman Gillmor and the subcommittee for the opportunity to share my concerns regarding the implementation of the Food Quality Protection Act of 1996. I also have the privilege of sharing with you a letter containing the perspective of thirteen county Farm Bureau presidents in Representative Gillmor's district and I ask to have it included in the record.

OVERVIEW

The Farm Bureau and its members dedicated time and effort to communicating the benefit of the passage of the Food Quality Protection Act (FQPA). For years we struggled with the unworkable Delaney Clause which specified zero tolerance for pesticide residue on food products. As technology improved and our ability to detect residues increased, zero tolerance became infeasible and unrealistic. Implementation of FQPA by the Environmental Protection Agency (EPA) however may result in unnecessary restrictions or cancellation of many of the critical crop protection products used in agriculture. As EPA proceeds with the reevaluation of tolerances as required by FQPA, it is vital that it not base these adverse actions against an existing tolerance on unreasonable or unreliable assumptions, sketchy information or unrealistic models, in place of sound scientific data and policies.

Ohio agriculture is a $73 billion component of the state's economy and is important to its continued viability. Here in Representative Gillmor's district, agriculture accounts for $6.6 billion in economic output and employees nearly 81,000 Ohioans. We have a unique agriculture in Ohio with typical Midwestern production of grains and oilseeds produced along side a wide variety of vegetables, fruit, mushrooms and even wine production. Livestock is an integral part of our agricultural economy, depending upon the production of feedstuffs and the proximity to the eastern market. Yet, virtually all of Ohio agriculture is, in some form or another, dependent upon crop protection products for its success and will be affected by the decisions EPA makes in determining the process by which these important tools will be reviewed.

Assuring that this process is done correctly is a top priority for the Ohio Farm Bureau Federation. To date, our fruit and vegetables growers have been most affected with the current review of the organophosphates (OPs), the most highly used insecticides in the United States. An Ohio Farm Bureau Federation-conducted survey of Guthion (azinphos methyl) use indicated that Ohio's fruit and vegetable producers depended upon its use to control pests on 22 Ohio crops; U.S. EPA plans to cancel 18 of these uses. This past week EPA and registrants negotiated cancellation of 23 uses of Guthion including many in Ohio. Growers indicated significant losses would result from the cancellation of this product given the zero to limited alternatives available.

In December 1999, EPA conducted their preliminary risk assessment for Lorsban (chlorpyrifos). Ohio agricultural producers count on Lorsban insecticide to defend more than 30 different crops from insect attack. In Ohio, where corn rootworm is the primary insect problem for corn growers, Lorsban is the most effective and safe product to control this damaging pest and is vital to soybean growers' control of spidermite outbreaks. While we are appreciative that EPA chose to eliminate household and residential uses rather than agricultural uses, it highlights our concern for corn and soybean growers.

As FQPA implementation moves forward, our concern rests with the understanding that OPs are just the first pesticide class to be subject to review and reassessment. As other pesticide classes are reviewed, the reassessment will be approached in much the same manner and adhere to the same policies currently under development. How these policies are developed is crucial and must be health protective without being unnecessarily conservative.

If these policies are not correctly developed and fail to follow sound methodologies and utilize good data during this first round, inadequacies in the approach will only be magnified in subsequent reviews. According to the EPA website there are 13,000 tolerances to be reassessed. To date only a little over 3,800 have undergone review. Yet to be reassessed are the bulk of pesticide uses, many of which are crucial to agricultural production.

The Ohio Farm Bureau Federation takes food safety seriously. We understand that the consequence of not being suitably conservative in estimating the effects of pesticides are serious and we believe they are understood. However, the risk of being too conservative is very real. The production of a safe, nutritious, abundant and affordable food supply depends upon the use of pesticides. Restrictions that negatively affect the availability and affordability of food means less access to the healthful foods necessary to a good diet. This kind of negative impact also disproportionately affects lower income families who already struggle to provide an adequate supply of fresh fruits and vegetables for their children.

Any approach to pesticide risk assessment must be based on sound, not speculative theoretical principles, must incorporate the highest quality data, and have an appropriate—but not excessive—degree of conservatism.

PROCESS CHALLENGES

The primary policy approaches that are a concern to agricultural producers are: assuring the use of good data and methodologies, a fair and transparent decision-making process that is open for public involvement, and an unacceptable practice of using unduly conservative endpoints, safety factors and default assumptions. EPA must give higher priority to making sound scientific decisions than to completing final tolerance reassessments by statutory deadlines and must develop a clear strategy for transition and risk mitigation. EPA must redress the current resource imbalance between tolerance reassessment and new chemical/new use registration and accelerate the pace of making decisions on new products and uses.

I am not a scientist and leave others to explain the very real concerns we have with assuring the use of sound methodologies. I, however, can understand the problems of indiscriminately applying extra safety factors to products that are already subject to considerable safety adjustments. I also have trouble understanding why EPA is advocating regulating pesticides at the 99.9 percentile when it means going to extreme efforts to protect such individuals as infants who consume eight pounds of grapes per day or two quarts of apple juice AND two quarts of pear juice a day. Further, these are very unlucky people who just happen to select grapes and juice that have the maximum residue allowed on products. To compound the problem, this data can not even be corroborated.

The lack of transparency (or the lack of clarity) on how decisions are being made by EPA on conducting reviews of products is a grave concern to the agricultural producers. Too often decisions are being made before the process is approved on how the decisions will be made. Compounding this difficulty is EPA's apparent rush to

complete the next phase of FQPA implementation, the cumulative risk assessment, by August 3, 2002. The pressure to complete this phase is brought by the need to meet the next statutory deadline in FQPA and to meet a deadline in a settlement decree with the Natural Resources Defense Council that was signed in the 11th hour of the Clinton Administration. As much as we would like to be, farmers, and the public, are not typically comfortable just trusting that everything will be resolved satisfactorily.

We believe that if common sense and sound data and methods are employed, there will be very few, if any, losses. However, in the event that uses are lost, there is currently no strategy in place for how EPA will decide which products and uses will be eliminated. The policy dictating how this risk mitigation will be conducted should have been determined before the first use was cancelled. It was not and this process still has not been identified. Today agricultural producers have faced, and are facing, cancellations with no idea how EPA arrived at which uses to cancel.

My final concern with the FQPA implementation process involves how EPA anticipates transition will occur when and if cancellation and restriction decisions are made. To date, EPA lacks a strategy for how to address transition, or the move to other pest control tools and methods. As discussed earlier, it is our belief that with the incorporation of sound science in the implementation process, transition will not be necessary, but if it is, it is imperative that users of these products know and understand what process EPA plans to use to facilitate transition to other products.

Transition, however, will require products to which agricultural producers can switch. With its focus on FQPA implementation, EPA has had a very real slow-down in the registration of new products. With fewer new products being registered, new alternatives are not available to farmers. Further, these alternatives must be economically feasible. Trading off an effective, affordable crop protection product for a more expensive pesticide that does not offer the same level of protection is not realistic for the continued competitiveness of U.S. and Ohio agriculture.

I have already referenced that EPA is now moving into the next phase of FQPA implementation with its cumulative risk assessment. It is an excellent example of the concerns I have outlined. Rather than follow the current course, a common-sense approach would dictate that EPA avoid the use of extreme toxicity endpoints, population percentiles and added safety factors and combining these policies to unnecessarily restrict uses. It makes sense that EPA use an appropriate 100-fold safety factor that protects our sensitive population not apply an unneeded additional safety factor that would add no real protection but would wipe out registered uses. EPA should join with every other regulating agency and world organization and reject the 99.9th percentile as the basis for regulation. Numerous scientific institutions show that regulating at the 99.9th percentile is no more protective of the health of sensitive members of our population, than regulating at a slightly lower percentile. Finally, EPA should explain what process it will use to address "risk", if any, resulting from a refined cumulative risk assessment.

While I am not an expert in these particular areas, I am an agricultural producer who is concerned that EPA's arbitrary policy calls, and not scientifically reviewed approaches explained with data, will determine if I have the tools I need to produce a safe, affordable, nutritious supply of food.

In all of these areas of concern—use of sound science, transparency, risk mitigation, transition, and new product registration—there is no process by which stakeholders—particularly interested and impacted growers such as myself—can participate. If mitigating risk by eliminating products and uses is necessary, there is no process by which I can provide input on the uses and products that may have to be changed or lost and the consequences of such actions on the farmer.

HOW FQPA AFFECTS FARMING OPERATIONS

I have reviewed concerns with the process by which EPA is implementing FQPA. Please allow me to share how these actions impact the agricultural industry in Ohio.

The agricultural industry in Ohio and the United States is experiencing intense economic pressure and competition from agricultural producers throughout the globe. Once our competitors were found in the next county or state and federal regulations impacted us all equally. However, with farmers in Argentina and Brazil vying for our domestic, as well as international, customers we can not afford to continue handing them the competitive advantage of restricting our production tools while importing their corn and soybeans produced with those very same tools.

On our farm we primarily raise corn and soybeans. In corn production we utilize herbicides to control broadleaf weeds. Without herbicide application our yields would be considerably cut—we would anticipate losing at least 50 percent of our

corn crop, which on a 100-acre cornfield would cost approximately $7,000. Further detracting from the value of the corn produced is the high level of weed seed in the grain and a decline in quality, both of which would result in a reduction in price.

To control weeds and produce a high quality crop, use Atrazine, an effective, affordable broadleaf herbicide. Losing Atrazine would devastate our weed control program. Very few other products are available that do not contain this effective product and those that are often recommend their use in tandem with this affordable product. One product, Balance Pro (isoxaflutole), is recommended to be used in conjunction with Atrazine, is much more expensive to use. Compared to the $3.00 per acre cost of Atrazine, Balance Pro costs me over $10.00 per acre—an increase of $7.00 per acre in input cost.

A loss of insecticides would also impact my ability to control the development of pest resistance. One of more important broad spectrum, post-emergence products is Warrior. It is used to control a variety of pests, including armyworm, earworm, aphids, cutworms and others. To get the same control, I would need to apply a combination of pesticides, increasing my costs by $4.00 to $7.00 per acre in product alone. Added to that cost is the additional expense of multiple applications. Further one product that would be a part of the combination would be the use of Capture, an insecticide that must be applied to the soil at planting time. This product must be applied at a time that precedes my ability to determine if I will have insect problems for the year. Warrior is applied only after evidence of insect damage appears.

As you can see, when these broad-spectrum, ineffective, inexpensive tools are taken away from Ohio and U.S. farmers, it costs significantly more to produce our crops. Use of these same tools by growers in other countries keep their input costs stable, placing domestic farmers at a disadvantage and making it more difficult to compete in the global market.

If we are importing food products, whether they are grains, oilseeds, or fruits and vegetables, that are produced using the very tools that were eliminated because of a concern over safety, are we really protecting our consumers? The fruit and vegetable industry has seen huge increases in imports. Overall imports of fruits and vegetables, fresh and processed, have increased from 9.5 percent of U.S. consumption in 1977-79 to 20.1 percent in 1999. (All data on market shares are from ERS-USDA.) Imports play a much larger role in the overall fruit market, 33.6 percent in 1999, than in the vegetable market, 10.1 percent in 1999. Does handing this kind of competitive advantage to our competitors truly result in an increase of food safety or does it simply reassign our food production offshore?

PROPOSED SOLUTION

We ask EPA to employ common sense in its approach to FQPA. A reasonable approach to the implementation of the Food Quality Protection Act, based on real data and not theoretical risk should result in a workable outcome with few adverse impacts. We must have a balanced, workable and transparent implementation of the Food Quality Protection Act based on sound science. Regulatory decisions must be made using reliable information and actual data; they must not disrupt agricultural production and not undermine our competitiveness in international markets.

Transparency in the process of how EPA is reviewing these products and opportunities for stakeholder participation is vital. There needs to be a transparent process established with affected stakeholders' input before any risk mitigation is contemplated.

We must have workable strategies on how EPA will mitigate risk and select what uses will be lost as well as how transition will occur. The availability of affordable effective alternatives should be considered when uses are cancelled; including the cancellations arrived at by negotiating with registrants.

We ask Congress to increased funding for USDA's Office of Pesticide Management Programs and other FQPA activities. USDA was intended to be a full partner in the implementation of this law, but a lack of funds and focus have made USDA unusually quiet on this issue. We depend upon the experts at USDA to communicate information regarding how crop protection products are used, how food products are handled, and tracking residue levels on domestic and imported food. This communication does not appear to be happening.

I ask for some analysis of how it is affecting the marketplace and our ability to compete in both the domestic and international markets. This analysis should determine whether FQPA is resulting in unintended consequences such as an increase in imports, a competitive disadvantage with our international customers and ultimately, economic failures of U.S. farmers without the intended benefit of enhanced food safety.

I appreciate the attention of the Subcommittee for the Environment and Hazardous Materials and ask for your continued consideration. Congressional involvement and oversight is needed to ensure that EPA's decisions are reasonable, well supported by reliable information and balanced as intended by Congress when FQPA was passes. We cannot afford to further disadvantage U.S. and Ohio farmers and turn over food production to the rest of the world as a result of the lack of sound science in our regulatory actions.

Thank you for the opportunity to address you here today.

Mr. GILLMOR. Thank you, Mr. McClure. Ms. Schmenk.

STATEMENT OF CHRISTIANE W. SCHMENK

Ms. SCHMENK. Thank you very much, Chairman Gillmor, for inviting me to testify today. My name is Chris Schmenk and I am Director of Environmental Stewardship for The Scotts Company. Scotts is headquartered in Marysville, Ohio, which is just a couple of hours south of here, and was founded there in 1868. We employ approximately 1,000 employees here in Ohio and about 3500 worldwide. Scotts is the world's leading producer and marketer of products for the do-it-yourself home and garden care market, and we also have an emerging lawn care business. Our brands include Turf Builder, Miracle-Gro, Ortho, Roundup, Osmocote and Hyponex. I will therefore speak to you today, both as a formulator of products registered with the EPA and as an end-user as well. Regarding the format of my testimony, I will first express concerns that Scotts, as a member of the industry, has with the implementation of the FQPA. I will then speak to you as a representative of an Ohio-based residential use company that depends on sound regulation to stay in business. Finally, I will conclude my comments with specific recommendations for the committee to consider in light of the approaching FQPA deadlines.

Regarding the implementation process, Scotts has been involved since the Act was enacted in 1996. The EPA has been willing to include Scotts and industry from the beginning and we are very appreciative of that. We have found a genuine willingness at the Agency to listen to our positions and to involve us in decision-making. We support the law's goals to provide additional protection for children, as well as new assessments regarding aggregate and cumulative exposure.

However, from the beginning of the implementation process, it became clear that many of the FQPA's new requirements could not be met for many years because the science needed to implement many of the law's provisions had not yet been developed. As of today, a great deal of the science still has not been developed, despite the hard work of both the EPA and pesticide registrants. Scotts is very concerned that as we near those impending deadlines, most notably the August 3, 2002 deadline for the cumulative risk assessments of OPs, we will needlessly lose the use of important pest management tools. Scotts works hard to ensure that our products meet the highest possible safety standard. As you know, all products registered before 1984 have to go through a reregistration and tolerance reassessment process that is as rigorous as the process for registering new products. This is part of a superb regulatory system that ensures the highest possible standards of safety for all citizens, particularly our children. The pesticide review process was excellent before 1996 and it is even stronger today. How-

ever, we are concerned that in recent years decisions about registered uses of pest control products may not have been entirely based on science. Anti-chemical emotions seem to have caused science to be disregarded in certain instances. Today, we ask for your help in ensuring that approved uses of safe and reliable pest management tools are not lost, and that all decisions made are based on scientific evidence.

I would like to next speak briefly on the use of data that has been developed by registrants. Scotts has been a leader in acquiring and delivering data to the EPA to support the continued registration of residential use pesticides. Scotts joined and is an active participant in the Outdoor Residential Exposure Task Force and we have also participated in a Residential Exposure Joint Venture Task Force in order to generate accurate data about adult and child exposures. The EPA has incorporated some registrant-generated data into its risk assessments; however, there are still instances in which the EPA is using default assumptions rather than the available, reliable data that has been generated by these task forces and individual pesticide registrants.

We hope that the EPA will incorporate this and other actual data in making their decisions, rather than using these default risk assumptions in order to more accurately assess exposures.

Next, I would like to talk briefly about overly conservative assumptions. Another concern that Scotts and members of industry have is that the residential portion of the process established by the FQPA for risk assessment includes several overly conservative assumptions that when fully incorporated into a risk assessment will eliminate many important pest control tools. For example, the EPA currently uses an oral hand-to-mouth exposure scenario to estimate the amount of exposure that a child may receive from touching a treated surface, such as a lawn or carpet and then placing his or her hand in their mouth. Our concern as a formulator and user of outdoor pest control products is that the EPA's exposure estimates were based on the results of an indoor videography study. The reality is that studies show that outdoor play results in children putting their hands in their mouths far less frequently than passive indoor activities.

This is just one example of where the EPA has over-estimated residential exposure, resulting in the risk cup becoming fuller unnecessarily. The Outdoor Residential Exposure Task Force will be submitting actual data to the EPA on outdoor hand-to-mouth activity in April. It is essential that this actual data be incorporated into the final OP cumulative risk assessment.

I will next comment briefly on two additional undecided science issues that could greatly impact the EPA's cumulative risk assessment. And these are the percentile of regulation and the application of the FQPA uncertainty factor.

The decisions made in the cumulative risk assessments depend, in large part, on how the EPA chooses to address these and other science policy issues. My colleague, Mr. McClure, spoke previously on the level of regulation, so I will not spend much time on that, but I will just comment that no other regulatory agency in the United States or the World Trade Organization regulates at the 99.9 percentile. Statisticians find no statistical difference between

the 99.9 and 99.5 percentile and, according to the CDC and the USDA, current food consumption data used by the EPA in pesticide risk assessment cannot be used to reliably predict consumption percentiles over the 95th percentile. If the EPA uses a 99.9 standard for the cumulative assessments, uses and products could be unnecessarily lost without providing any additional protection of public health.

Regarding the FQPA uncertainty factor, the FQPA provided that if the EPA lacks complete and reliable data to assess the risk of pesticides on infants and children, it could add a safety or uncertainty margin of ten-fold. The EPA has not yet decided whether it will add an additional tenfold uncertainty factor to the overall cumulative assessments for the OPs. The Agency could choose to add anything from an additional 2 to a 10 times factor.

As I previously stated, the uncertainty factor was intended for use when there was a lack of reliable or incomplete data. However, that is not the case for OPs. The EPA has more than adequate amounts of data on how OPs work and there is no uncertainty about the common mechanisms for which they are being grouped together. Therefore, there is no need for an additional uncertainty factor to be applied.

Finally, Scotts is concerned about the timing of these science decisions. The EPA committed through CARAT to release a revised risk assessment methodology for public comment in June. While Scotts greatly appreciates the EPA's commitment to release this for public comment, it would have been much more timely for all stakeholders if it had been released earlier this spring. A June release will not provide adequate time for the EPA to meaningfully assess all public comment submitted and to make any appropriate or necessary changes before the August 3 deadline.

Finally, I will speak about Scotts in particular. Scotts has felt firsthand the impact of the FQPA. In 2000, residential uses of two key pest control active ingredients, chlorpyrifos and diazinon were voluntarily canceled during the tolerance reassessment process due to fears of the registrants that they could not meet the incredibly high theoretical risk hurdles set by the EPA when faced with impending deadlines. These were broad-spectrum ingredients that effectively controlled a wide range of pests. The number of remaining active ingredients that can effectively manage the pests controlled by these two product is extremely limited.

Scotts not only was required to reformulate various products in our do-it-yourself business to replace these effective ingredients, but we also lost the use of them in our lawn care service business. Since there are no replacements that last as long or are as effective, we have to make more applications of a wider variety of pesticides in order to properly control pests. We estimate that our costs will rise at a minimum of 25 percent and perhaps as much as 50 percent in our lawn care service business.

It is essential that other key active ingredients are not lost unnecessarily by the use of exaggerated default assumptions rather than reliable data.

Scotts understands the pressures faced by the EPA and we have been able to work cooperative with the Agency regarding the discontinuance of two other OPs for use on lawns, malathion and

acephate. Fortunately, there were acceptable substitute pest controls for use on lawns available to replace these, so the public was not unduly harmed. However, we are also concerned on a broad scope, as I think said by the previous witness, by the harmful precedence that might be set if the EPA does not use sound science in its assessment of OPs. Other classes of pest control products are currently or soon will be assessed under the FQPA. And if actual data is not used and overly conservative default assumptions are used instead, we will lose the ability to provide effective pest control products to our customers.

In conclusion, I would like to thank the committee for holding this hearing and I would like to ask for your assistance in several areas. It is essential that as the EPA moves forward with FQPA implementation, that you offer them your support so that they continue to do the following:

To use accurate, real-world data and sound science, rather than hypothetical models and exaggerated exposure assessments.

And second, that you ask them to consider and incorporate all available actual data into the tolerance reassessment process even though there is an August 3 deadline approaching. If this approaching deadline causes this data not to be used, it could result in the further loss of effective, safe and thoroughly tested products. It is important to remember that these products are used for a reason, to control pests, and that true pest management is not possible without these tools. Removing these tools from the market will hurt our economy, will hurt businesses like Scotts, will needlessly expose children to pests and will deny consumers access to safe pest control choices.

Thank you.

[The prepared statement of Christiane W. Schmenk follows:

PREPARED STATEMENT OF CHRISTIANE W. SCHMENK, THE SCOTTS COMPANY

Thank you very much, Chairman Gillmor, Congressman Pallone and other members of the subcommittee for inviting me to testify today. My name is Chris Schmenk, and I am Director of Environmental Stewardship for The Scotts Company. Scotts is headquartered in Marysville, Ohio and was founded there in 1868. We employ approximately 1000 employees in Ohio and about 3500 worldwide. Scotts is the world's leading producer and marketer of products for do-it-yourself lawn and garden care. Our products and brands include Turf Builder, Miracle-Gro, Ortho, Roundup, Osmocote and Hyponex. We also have an emerging lawn care business for those who would rather hire us to apply their lawn, tree and shrub care products. I will therefore speak to you today as both a formulator of products registered with the EPA and as an end-user of products. Regarding the format of my testimony, I will first express concerns that Scotts, as a member of industry, has with the implementation of the Food Quality Protection Act (FQPA). I will then speak to you as a representative of an Ohio-based company that depends on sound regulation to stay in business. Finally, I will conclude my comments with specific recommendations for the Committee to consider in light of approaching FQPA deadlines.

IMPLEMENTATION PROCESS

As a formulator of numerous specialty pest control products, Scotts has been involved in the FQPA implementation process since President Clinton signed the bill into law in 1996. The EPA has been willing to include Scotts and industry in the implementation process from the beginning, and we are very appreciative of that. We have found a genuine willingness at the Agency to listen to our positions and to involve us in decision-making. When the FQPA was originally passed, Scotts and other registrants and users of pesticides were aware that the law's new requirements would require registrants to perform additional tests and gather new data concerning pesticide use and exposure. While we support the law's goals to provide

additional protection for children, as well as new assessments regarding aggregate and cumulative exposure, we also recognize that the law gave the EPA a vast amount of discretion on how to implement these goals.

From the beginning of the implementation process, it became clear that many of FQPA's new requirements could not be met for many years simply because the science needed to implement many of the law's provisions had not yet been developed. Almost six years later, a great deal of the science has still not been developed, despite the hard work of the EPA and pesticide registrants. Scotts is very concerned that as we near impending deadlines imposed by the FQPA, most notably the August 3, 2002 deadline for the cumulative risk assessment of organophosphates (OP's), we will needlessly lose the use of important pest management tools. Scotts spends an enormous amount of time and energy to make sure our products meet the highest possible safety standards. It is clear that the pesticides on the market today are rigorously tested before approval and do not pose health threats to the public. The average pesticide takes over 10 years to register and must pass over 110 vigorous tests conducted under stringent laboratory practices mandated by the EPA. On average, the development of new pesticide products can cost up to $150 million to get from the lab to the market.

All products registered before 1984, have to go through a reregistration and tolerance reassessment process that is as rigorous as the process for registering new products. This system of registration and reregistration is part of a superb regulatory system that insures the highest possible standards of safety for all citizens, particularly our children. The pesticide review process was excellent before 1996 and is even stronger today. Scotts supports the continued strengthening of this process, and we have no interest in selling or using any products that pose hazards to our customers. We are also very much in favor of a safe food supply for our nation. However, we are concerned that in recent years, decisions about registered uses of pest control products may not have been based entirely on science. Anti-chemical emotions seem to have caused science to be disregarded in certain instances. Today, we ask for your help in ensuring that approved uses of safe and reliable pest management tools are not lost, and that all decisions made are based on scientific evidence.

DATA DEVELOPMENT

The Scotts Company has been a leader in acquiring and delivering data to EPA to support the continued registration of residential-use pesticides. Scotts joined and is an active participant in the Outdoor Residential Exposure Task Force (ORETF) and participated in the development of the Residential Exposure Joint Venture Task Force (REJV) in order to generate accurate data about adult and child exposures to pesticides used in and around the home and on lawns, gardens, golf courses, and playgrounds. The EPA has incorporated some registrant-generated data into its risk assessments; however, there are still instances in which the EPA is using default assumptions, rather than the available, reliable data generated by ORETF, REJV and individual pesticide registrants.

Additional ORETF data on hand-to-mouth activities of small children is scheduled to be submitted to the EPA in mid-April, but we are fearful that this data will not be able to be incorporated in Agency decisions about OP's, in the rush to meet statutory and court-ordered deadlines. We hope that the EPA will incorporate this and other actual data generated in the near future into its final risk assessments of OP's, rather than using default risk assumptions, in order to more accurately assess exposures. Statutory and court-ordered deadlines for implementation of the FQPA requirements must not be an excuse to disregard reliable data generated by registrants. We are all learning in this implementation process, and the task of putting together mathematical models to assess risk has been enlightening to both industry and the Agency. In order to avoid the needless loss of pesticide uses, the implementation process should allow the EPA to be flexible so that it can use these real data, rather than exaggerated default assumptions.

OVERLY CONSERVATIVE ASSUMPTIONS

Another concern that we would like to bring to your attention is that the residential portion of the process established by the FQPA for cumulative risk assessment includes several overly conservative assumptions that when fully incorporated into a risk assessment would eliminate many important pest control tools. For example, the EPA currently uses an oral hand-to-mouth exposure scenario to estimate the amount of exposure a child may receive from touching a treated surface such as a lawn or carpet and then placing his hand in his mouth. Our concern as a formulator and user of outdoor control products is that the EPA's exposure estimates were

based on the results of an indoor videography study. The study only considered the frequency of hand-to-mouth occurrences of children playing indoors, yet it has been used to estimate hand-to-mouth occurrences for children playing both indoors and outdoors. The reality is that studies show that outdoor play results in children putting their hands in their mouths far less frequently than passive indoor activities. ORETF will be submitting actual data to the EPA on outdoor hand-to-mouth activity in April. It is essential that this type of data be incorporated into the final OP cumulative risk assessments.

The EPA's assessments have assumed that when children play on turf, they pick up 5% of any pesticide residue present each time their hands come into contact with the turf, and that this 5% is subsequently ingested, resulting in an ingestion of 5% of all of the pesticide that had been applied. Scientific analysis shows that this 5% figure is greatly over-stated.

These examples are just a few ways in which the EPA's OP cumulative assessment overestimates residential exposure, resulting in the "risk cup" becoming fuller unnecessarily. Reliable data, not default assumptions, must be used to ensure that the risk cup is not filled with unsubstantiated "theoretical risk." Scotts is very concerned that if this reliable data is not used, our uses of these control tools will be lost.

I would also like to take this opportunity to comment on two additional undecided science issues that could greatly impact EPA's cumulative risk assessments—the percentile of regulation and the application of the FQPA uncertainty factor. The impact of the cumulative risk assessment on the availability of vital pest control uses depends in large part on how EPA chooses to address these and other science policy issues. Both of these decisions are policy calls that the EPA will make in the next few months, and they will determine whether key products remain available to Ohio companies such as Scotts.

PERCENTILE OF REGULATION

When we speak of the level of regulation, we are referring to the percentage of the population used in exposure estimates. If the EPA bases exposure estimates on 99.9 percent of the population, as it did in the individual chemical assessments under the FQPA, risk mitigation will appear to be necessary, even though no additional protection is needed. No other regulatory agency in the United States or the World Trade Organization regulates at the 99.9th percentile. Statisticians find no statistical difference between the 99.9 and 99.5 percentiles, and according to the CDC and the USDA, current food consumption data used by the EPA in pesticide risk assessment cannot be used to reliably predict consumption percentiles over the 95th percentile. If the EPA uses a 99.9 standard for the cumulative assessments, uses and products could be unnecessarily lost without providing any additional protection of public health.

Further, EPA's current practice of combining the maximum exposures from each exposure route to represent the combined exposure for the population is another area of concern. A child with dermal exposure from treated turf at the 99.9th percentile is probably not the same child whose hand-to mouth oral exposure is at the 99.9th percentile and is also not the same child whose dietary exposure is at the 99.9th percentile. Combining these exposure values to represent a single child at the 99.9th percentile is needlessly overprotective since such an individual is unlikely to exist. This overly-conservative practice, combined with the safety factors and the percentile of regulation used in cumulative assessments will result in additional, unnecessary loss of safe and effective products for the residential environment.

FQPA UNCERTAINTY FACTOR

EPA's application of the FQPA Uncertainty Factor is another science policy issue that could result in the needless cancellation of pesticide uses. According to a February 28, 2002 EPA draft guidance document, "Consideration of the FQPA Safety Factor and Other Uncertainty Factors in Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity," the EPA will continue to make decisions about whether or not to apply additional safety factors on a case-by-case basis. The draft goes on to state that this "individualized determination" may include the application of the FQPA uncertainty factor to individual chemicals, as well as the entire common mechanism pesticide group.

EPA has not yet decided whether it will add an additional 10x uncertainty factor to the overall cumulative assessment for the OPs. The agency could choose to add anything from an additional 2-10x factor. The uncertainty factor was intended for use when there was uncertainty about the database for a particular type of chemistry. In the case of organophosphates, there is no uncertainty about the common

mechanism of toxicity -- cholinesterase inhibition. The EPA has more than adequate amounts of data on how organophosphates work, and there is no uncertainty about the common mechanism for which they are being grouped together. For the cumulative OP risk assessment, there is no need for an additional uncertainty factor to be applied.

The EPA committed to the Committee to Advise on Reassessment and Transition (CARAT) to release a revised risk assessment methodology for public comment in June. This assessment will include determinations about the level of regulation and the application of the FQPA uncertainty factor. While Scotts greatly appreciates the EPA's commitment to release the revised methodology for public comment, it would have been much timelier for all stakeholders if the EPA had released the refined assessment process earlier this spring. A June release will not provide adequate time for the EPA to meaningfully assess all public comments submitted and to make appropriate changes to the risk assessment process by the August 3rd deadline.

PRODUCT LOSS BY SCOTTS

Scotts has felt first-hand the impact of the FQPA. In 2000, residential uses of two key pesticide active ingredients—chlorpyrifos and diazinon- were voluntarily cancelled during the tolerance reassessment process due to fears of the registrants that they could not meet the incredibly high theoretical risk hurdles set by the EPA when faced with impending deadlines. These were broad-spectrum ingredients that effectively controlled a wide range of pests. The number of remaining active ingredients that can effectively manage the pests controlled by these two products is extremely limited.

Scotts not only was required to reformulate various products in our do-it-yourself business to replace these effective ingredients, but we also lost the use of them in our lawn care service business. Since there are no replacements that last as long or are as effective, we have to make more applications of more pesticides in order to properly control pests. We estimate that our costs will rise at a minimum of twenty-five percent, and perhaps as much as fifty percent. It is essential that other key active ingredients are not lost unnecessarily by the use of exaggerated default assumptions, rather than reliable data.

Scotts understands the pressures faced by the EPA, and we have been able to work cooperatively with the Agency regarding the discontinuance of two other organophosphates for use on lawns, malathion and acephate. Fortunately, there were acceptable substitute pest controls available to replace these, so the public was not unduly harmed by these lost uses. However, in many cases, there are no substitutes available, and we are concerned about the ability to properly control harmful pests if we lose important products.

CONCLUSION AND RECOMMENDATIONS

In conclusion, I would like to thank the Committee for holding this hearing and to ask for your assistance in several areas. It is essential that as the EPA moves forward with FQPA implementation, that you offer them your support so that they can continue to do the following:

- Use accurate real-world data and sound science, rather than hypothetical models and exaggerated exposure assessments;
- Consider and incorporate all available data into the tolerance reassessment process, even though there is an August 3 deadline. If this approaching deadline causes such data to not be used, it could result in the loss of effective, safe and thoroughly tested products. It is important to remember that these products are used for a reason—to control pests—and that true pest management is not possible without these tools. Removing these tools from the market will hurt our economy, will hurt businesses like Scotts, will needlessly expose children to pests and will deny consumers access to safe pest control choices.

Thank you.

Mr. GILLMOR. Thank you. Mr. Marquette.

STATEMENT OF ROBERT MARQUETTE

Mr. MARQUETTE. Thank you. Good morning, Chairman Gillmor. Chairman Gillmor and members of the subcommittee, my is Robert Marquette and I am the owner of Ram Exterminators in Oregon, Ohio. I am testifying this morning as President of the Ohio Pest Control Association and a member of the National Pest Manage-

ment Association. The National Pest Management Association represents 5,000 pest management companies across the United States, 122 of those companies are located right here in Ohio.

Like pest management companies across Ohio and the rest of the country, Ram Exterminators is a small family owned business that manages pests such as ants, cockroaches, rodents, spiders, stinging insects and termites in countless different settings. Those settings include single and multi-family dwellings, office buildings, hospitals, nursing homes, restaurants and many other types of locales.

I appreciate the opportunity to testify this morning. I will outline the impact that FQPA has had on our pest management industry and express the industry's concerns about the manner in which the U.S. EPA has implemented FQPA, particularly during the previous administration. I will also discuss the industry's perspective on cumulative risk assessments.

First off, I think it is important to note that the pest management industry strongly supported FQPA when it was enacted in the summer of 1996. We supported the stringent health-based standards established by FQPA and were hopeful that the law's emphasis on using sound science and reliable data to formulate policy would dictate the Agency's decisionmaking process. While EPA's FQPA-related decisions have not been as rooted in sound science as pest management industry would like, we are hopeful that the current administration will be more committed to implementing FQPA as Congress originally intended, and look forward to working closely with Mr. Sharp and other Agency officials.

As you all well know, FQPA dramatically changed the way EPA evaluates registered pesticides. A pesticide use is no longer looked at on an individual basis. Specifically, FQPA requires EPA to make determination "that there is a reasonable certainty that no harm will result from aggregate exposure . . . including all anticipated dietary exposures and all other exposures for which there is reliable information." One of the other types if exposures that must be included in an aggregate assessment is residential exposure, which covers pesticides used in and around residences.

Residential exposure was not required prior to 1996. As a result, such data was not widely available. Even EPA acknowledges that the lack of residential exposure data noting in a January 4, 1999 Federal Register notice that "Highly specific residential exposure data [is] generally lacking, and there is not wide understanding and acceptance of existing models and assumptions."

As recently as early this month, the Agency again acknowledged the scarcity of residential exposure data.

Fortunately, Congress recognized that certain data might not be immediately available. That is why Congress has expanded EPA's data call-in authority, allowing the Agency to compel manufacturers to collect and submit this data. Since FQPA passed, however, EPA has only exercised this data call-in authority once for residential use products. Despite the absence of reliable data, the Agency made significant decisions in 1999 and 2000 about the future availability of products that my company and other pest control operators in the United States use to safeguard our customers from dangerous, destructive and annoying pests.

Fewer FQPA decisions better illustrate the lack of reliable data that leads to the unwarranted loss of products than EPA's handling of the compound bendiocarb. Sold under the trade name Ficam, bendiocarb was first registered with EPA back in 1980. It had a strong safety record and was used to manage a multitude of pests, including yellow jackets, ants and spiders. In fact, Ficam was marketed as an excellent product to use in sensitive accounts such as hospitals and day care centers because it posed virtually no risk of exposure.

In the fall of 1999, however, EPA suddenly announced that it reached a voluntary agreement the manufacturer of bendiocarb to cancel all uses of the product December 31, 2001. This action resulted from the FQPA-driven assessment that relied heavily upon unrealistic worst-case scenarios. The industry felt that this process unfairly and unjustly painted Ficam in an unfavorable light. Relying on worst-case scenarios that suggested that the residential exposure risks were greater than they actually were led the Agency to request the manufacturer to conduct a series of additional and expensive toxicity tests.

Based on the relatively limited sales of Ficam, the manufacturer determined that the additional tests were not a worthwhile investment. Because of the Agency's reliance on worst-case assumptions, one of the industry's most effective tools has been lost. Ficam was especially effective in managing yellow jackets and other wasps. Now many operators are uncertain as to which product they are going to use to replace Ficam to manage these stinging insects, fearing poor results and increased liability. In August and September, the months that comprise the traditional yellow jacket season, will be the first since the loss of Ficam. I can only hope that my customers are not at a greater risk from the yellow jacket stings because a useful tools has been unnecessarily lost.

Regarding cumulative risk, pest management industry has a slightly different perspective than some of the others on this panel. The fact is that practically all the PCO uses of organophosphates were lost in the FQPA aggregate assessment, including diazinon, malathion, chlorpyrifos, acephate, DDVP and others. We are, however, extremely concerned about the precedent EPA will set with its cumulative risk policy for organophosphates. While our industry is fortunate enough to have some viable replacements for the organophosphates that have been lost, synthetic pyrethroids, one of the next classes of chemicals scheduled to be reviewed under FQPA, are a staple of our industry. Their loss would be truly devastating. But unless EPA collects data and refines its method for estimating risks from residential exposure, their losses are assured.

While I expressed numerous concerns during my testimony today, I am extremely hopeful that EPA Administrator Christine Todd Whitman will lead the Agency in a different direction that her predecessor. In fact, I would like to commend Administrator Whitman for being the first EPA Administrator to ever address a structural pest management group in Washington when she spoke to us at the National Pest Management Association last February. Her appearance before the FPMA gives me hope that Administrator Whitman is truly committed to opening dialog with all the

stakeholders and not just those that fit a particular political agenda.

Again, I appreciate the opportunity to testify and look forward to answering any of your questions.

[The prepared statement of Robert Marquette follows:]

PREPARED STATEMENT OF ROBERT MARQUETTE ON BEHALF OF THE NATIONAL PEST MANAGEMENT ASSOCIATION AND OHIO PEST CONTROL ASSOCIATION

Chairman Gillmor and members of the Subcommittee, my name is Bob Marquette and I am the owner of Ram Exterminators in Oregon, Ohio. I am testifying this morning as President of the Ohio Pest Control Association and a member of the National Pest Management Association. NPMA represents 5,000 pest management committees across the United States, 122 of which are located in Ohio.

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I appreciate the opportunity to testify this morning. I will outline the impact that the Food Quality Protection Act (FQPA) has had on the pest management industry and express the industry's concerns about the manner in which the U.S. Environmental Protection Agency (EPA) has implemented FQPA, particularly during the previous administration. I will also discuss the industry's perspective on cumulative risk assessments.

First off, I think it is important to note that the pest management industry strongly supported FQPA when it was enacted in the summer of 1996. We supported the stringent health-based standard established by FQPA and were hopeful that the law's emphasis on using sound science and reliable data to formulate policy would dictate the Agency's decision-making process. While EPA's FQPA related decisions have not been as rooted in sound science as the pest management industry would have liked, we are hopeful that the current administration will be more committed to implementing FQPA as Congress originally intended and look forward to working closely with Mr. Sharp and other Agency officials.

As you well know, FQPA dramatically changed the way that EPA evaluates and registers pesticides. A pesticide use is no longer looked at on an individual basis. Specifically, FQPA requires EPA to make a determination "that there is a reasonable certainty that no harm will result from aggregate exposure . . . including all anticipated dietary exposures and all other exposures for which there is reliable information." One of the other types of exposures that must be included in the aggregate assessment is residential exposure, which covers pesticide use inside residences and on lawns.

Residential exposure data was not required prior to 1996. As a result, such data was not widely available. Even EPA has acknowledged that it lacks reliable residential exposure data, noting in a January 4, 1999 *Federal Register* notice that "Highly specific residential exposure data are generally lacking, and there is not wide understanding and acceptance of existing models and assumptions." As recently as an EPA advisory committee meeting earlier this month, the Agency again acknowledged the scarcity of residential exposure data.

Fortunately, Congress recognized that certain data might not be immediately available. That is why Congress expanded EPA's data call-in authority, allowing the Agency to compel manufacturers to collect and submit data. Since FQPA passed, however, EPA has only exercised its data call-in authority once for residential use products. Despite the absence of reliable data, the Agency made significant decisions in 1999 and 2000 about the future availability of products that my company and other pest control operators used to safeguard our customers from dangerous, destructive and annoying pests.

Fewer FQPA decisions better illustrate how the lack of reliable data leads to the unwarranted loss of products than EPA's handling of the compound bendiocarb. Sold under the trade name Ficam, bendiocarb was first registered by EPA in 1980. It had a strong safety record and was used to manage a multitude of pests, including yellow jackets, ants and spiders. In fact, Ficam was marketed as an excellent product to use in sensitive accounts such as hospitals because it posed virtually no risk of exposure.

In the fall of 1999, however, EPA suddenly announced that it had reached a voluntary agreement with the manufacturer of bendiocarb to cancel all uses of the product by December 31, 2001. This action resulted from an FQPA-driven assess-

ment that relied heavily upon unrealistic worst-case scenarios. The industry felt that this process unfairly and unjustly painted Ficam in an unfavorable light. Relying on worst-case scenarios that suggested that residential exposure risks were greater than they actually were led the Agency to request that the manufacturer conduct a series of additional, expensive toxicity tests.

Based on the relatively limited sales of Ficam, the manufacturer determined that the additional tests were not a worthwhile investment. Because of the Agency's reliance on worst-case assumptions, one of the industry's most effective tools has been lost. Ficam was especially effective in managing yellow jackets and other wasps. Now many operators are uncertain as to which product they will use to replace Ficam to manage yellow jackets, fearing poor results and increased liability. This August and September—the months that comprise the traditional yellow jacket control season—will be the first since the loss of Ficam. I can only hope my customers are not at greater risk from yellow jacket stings because a useful tool has been unnecessarily lost.

Regarding cumulative risk, the pest management industry has a slightly different perspective than some of the others on this panel. The fact is that practically all the PCO uses of organophosphates were lost in the FQPA aggregate assessment, including, diazinon, malathion, chlorpyrifos, acephate, DDVP and propetamphos. We are, however, extremely concerned about the precedent EPA will set with its cumulative risk policy for the organophosphates. While our industry is fortunate enough to have some viable replacements for the organophosphates that have been lost, synthetic pyrethroids, one of the next classes of chemicals scheduled to be reviewed under FQPA, are a staple of our industry. Their loss would be truly devastating. But, unless EPA collects the data and refines its methods for estimating risks from residential exposure, their loss is assured.

While I have expressed numerous concerns during my testimony, I am extremely hopeful that EPA Administrator Christine Todd Whitman will lead the Agency in a different direction than her predecessor. In fact, I commend Administrator Whitman for being the first EPA Administrator to ever address a structural pest management group when she spoke at a National Pest Management Association meeting in late February. Her appearance before NPMA gives me hope that Administrator Whitman is truly committed to opening a dialogue with all stakeholders and not just ones that fit a political agenda.

Again, I appreciate the opportunity to testify and look forward to answering any questions you may have.

Mr. GILLMOR. Thank you, Mr. Marquette. Mr. Zellers.

STATEMENT OF JEFFREY ZELLERS

Mr. ZELLERS. Mr. Chairman, my name is Jeffrey Zellers, vice president of K.W. Zellers & Son, Inc., located in Hartville, Ohio. Our family grows, packs and ships fresh salad vegetables seasonally from the middle of May through the middle of October. These vegetables, produced on 1100 acres, are distributed throughout the eastern United States. And the gentleman from USDA referred to minor crops, I would be a producer of minor crops.

I appreciate the opportunity to testify and share with you concerns I have developed from following the implementation of the Food Quality Protection Act since its passage in 1996. I am a concerned agricultural producer who has responsibly used these products for years.

The process by which FQPA is implemented is critically important. Currently under review are the organophosphates, or OPs as a group, are the most highly used insecticides in the United States, and their use on my farm is extremely important in our ability to competitively produce a safe, affordable, nutritious product. OPs such as dimethoate, diazinon, chlorpyrifos or Lorsban and azinphos methyl, common name Guthion, are products crucial to our ability to effectively provide the quality of products our customers demand. It is crucial that the final version be health protective without being unnecessarily conservative.

While the consequences of not being sufficiently conservative in predicting the effects of pesticides are understood, it should be noted excessively conservative risk analysis could unnecessarily limit the availability of products essential to growing vegetables on our farm. This over-estimation could unintentionally increase the cost and reduce the availability of healthy vegetables as well as grains and fruits, poorly serving public health.

I am concerned about the unnecessary elimination of OPs and other crop protection products for several reasons: First, there is a current lack of alternatives for many of the products for which EPA is proposing cancellation. Guthion is one of the most important products used on our farm. We currently use it to control carrot weevils on curly and Italian parsley. The carrot weevil will burrow into the root of the parsley, destroying the root system and making the product's quality unacceptable to my buyers. These varieties of parsley gross $15,000 to $30,000 per acre and are subsequently amongst our most important crops. Pest control alternatives are available until our normal summer temperatures of 80 degrees Fahrenheit and above arrive. At those temperatures, Guthion is the only product that controls carrot weevils. EPA is proposing the immediate cancellation of Guthion use on parsley. And it is my understanding that that may have happened last week, I'm not clear on that, Mr. Chairman.

Second, I, along with other—with many producers throughout Ohio and the United States implemented integrated pest management program. This is a program designed to eliminate insect, disease and weed pest problems, not eradicate all pests. It means applying pesticides, fertilizers or irrigation only when the benefits outweigh the costs so we utilize less pesticide product and reduce a pest's likelihood of developing resistance to a particular product. In implementing an IPM program, we rotate the use of pesticides as well as consider other pest management options, including natural, biological and cultural methods.

When our pesticide options are reduced to simply one product to control a particular pest on a specific crop, our IPM program suffers and its benefit declines. Dimethoate is a critical tool used on our operation to control aster leafhoppers on leafy lettuces. When we have been unable to spray due to weather difficulties, aster leafhoppers which carry the infectious aster yellows virus have destroyed two-thirds of our lettuce corp resulting in a $4,000 loss per acre. Dimethoate is the most effective, affordable product and the only chemical that effectively controls this pest. We have access to Sevin, the only other product available for leafhoppers, but its repeated use results in resistance development among pests and kills all the friendly predator insects upon which we depend. Killing our friendly predator insects defeats the objective of an effective IPM program.

Third, competition from other nations in agricultural production continues to increase. And now I am facing restricted access to the same tools Canadian and other overseas growers have. As the broad-spectrum, inexpensive, effective tools I currently use are taken away from me, it costs me significantly more to grow my crops. Yet foreign growers are still able to use these materials, fur-

ther widening the competitive gap and my ability to compete in this global market, all without raising the level of food safety.

The competitive advantage we are handing to our international competitors through the current FQPA implementation path, we will continue to import more food where we have no control over how it is produced nor how the workers that help grow and harvest the crops are treated. To date, .7 percent of fresh fruits and vegetables are directly inspected. If no residue is found on imported fruits and vegetables, they are considered to have no residue. For U.S. products, if no residue is found, EPA still assumes that there is half the applied level of residue on the food product. Under current FQPA implementation, zero does not equal zero unless it is imported.

The intention of FQPA has been stated as enhancing the safety of our food supply. As a vegetable grower and a father of two young children, I would be the first person to support implementation if I believed it resulted in increased protection of our food supply. If sound science shows that the environment or public health is at risk, I will be the first one to campaign for cancellation of a pesticide.

Proposed solutions—a reasonable approach to the implementation of FQPA, based on real data and not theoretical risk should result in a workable outcome that does not disrupt agricultural production or undermine our competitiveness in international markets.

I ask for a common sense approach in reviewing these products and ask EPA to understand how products are actually used. EPA assumes that I use the maximum dosage of crop protection product the maximum number of times on each of my crops. This is simply not true. My goal is to control the pest, not eradicate them from my field. Oftentimes the very part of our crop that receives an application is never sold to the consumer.

We apply dimethoate to lettuce plants when they are young and most vulnerable to the aster leafhopper. As the plant grows, the outer leaves that received the application at least 21 days prior to harvest fall to the side and the lettuce is harvested without the outer leaves which remain in the field. In this case, zero residue really means zero residue.

Transparency in the process of how EPA is reviewing these products and the opportunities for stakeholder participation is vital. There needs to be a transparent process established with affected stakeholders' input before any risk mitigation is contemplated.

I ask for consideration of how FQPA is affecting the marketplace and agricultural production. An analysis should be done to ensure that we are not experiencing such unintended consequences as an increase in imported food or business failures of U.S. farmers with no additional improvement in the food supply. The safety of our population is not advanced if we simply reassign production to growers in other countries who do not fall under U.S. regulatory control.

I ask for your continued attention. Congressional involvement and oversight is needed to ensure that EPA's decisions are reasonable, well supported by reliable information and balanced. Unless FQPA is implemented carefully and in a practical manner, it will

cause great harm to agriculture and compound the economic difficulties that many farmers are currently facing.

Thank you for the opportunity to address you here today.

And I have a little blurb here if I might add, it was a quote that I thought was very interesting, it was in a vegetable grower magazine and the title or the article was "Phasing Out the OPs." The last line here, "The bottom line is that pest management without OPs is quite a bit more expensive. It is difficult to predict what sporadic or minor pests move to the role of key pests when OPs are removed." And I think that goes beyond just crop protection, it also goes to serving public health.

Thank you.

[The prepared statement of Jeffrey Zellers follows:]

PREPARED STATEMENT OF JEFFREY ZELLERS, AGRICULTURAL PRODUCER

Mr. Chairman and members of the Committee, my name is Jeffrey Zellers, vice-president of K.W. Zellers & Son, Inc. located in Hartville. Our family grows, packs, and ships fresh salad vegetables seasonally from the middle of May through the middle of October. These vegetables, produced on 1,100 acres are distributed throughout the eastern United States. We also operate four acres of greenhouse primarily growing bedding plants for the wholesale market. I am here today to share my concerns with the implementation of the Food Quality Protection Act of 1996.

I appreciate the opportunity to testify and share with you the concerns I have developed from following the implementation of the Food Quality Protection Act since its passage in 1996. I am not a scientist or a statistician, but am an agricultural producer who has responsibly used these products for years.

OVERVIEW

The agricultural community greeted the Food Quality Protection Act with enthusiasm because it replaced the unworkable Delaney Clause. However, implementation of the Food Quality Protection Act (FQPA) by the Environmental Protection Agency (EPA) may result in unnecessary restrictions or cancellation of some vital crop protection products. It is critical that as EPA proceeds with the reevaluation of tolerances as required by FQPA, that it not base restrictions or cancellations of an existing tolerance on unreasonable or unreliable assumptions, anecdotal information or exaggerated models, in lieu of sound scientific data and policies.

Getting this process right is critically important. Currently under review, the organophosphates (OPs) are, as a group, the most highly used insecticides in the United States, and their use on our farm is extremely important to our ability to competitively produce a safe, affordable, nutritious product. Dimethoate, diazinon, Lorsban (chlorpyrifos) and Guthion (azinphos methyl) are four OP products crucial to our ability to effectively provide the quality of products our customers demand.

But OPs are just the first class to undergo this process. Several other groups of pesticides will also soon undergo agency review, and the approach taken with this first group of crop protection products will, no doubt, have a large influence on the conduct of those later reviews. It is crucial that the final version be health protective without being unnecessarily conservative.

While the consequence of not being sufficiently conservative in predicting the effects of pesticides are understood, it should also be noted that there are potentially negative public health impacts of being too conservative in their review. The manufacture, storage, and transportation of the food we produce depend upon pesticide use to provide an abundant, nutritious, safe, and affordable food supply. Excessively conservative risk analyses could limit unnecessarily the availability of products essential to growing vegetables on our farm. Therefore, grossly overestimating the risk of these tools could unintentionally increase the cost and reduce the availability of healthful vegetables as well as grains and fruits, poorly serving public health. These pesticides are also often used in non-agricultural products that similarly benefit the public health and safety in a variety of ways.

It is therefore important to pursue an approach to pesticide risk assessment that is grounded on sound theoretical principles, incorporates the highest quality exposure information and toxicological data, and has an appropriate—but not excessive—degree of conservatism.

IMPACT ON FARMS

I am concerned about the unnecessary elimination of OPs and other crop protection products for several reasons. These reasons include: a critical lack of affordable alternatives available to control pests, the need for multiple products for successful integrated pest management (IPM) programs and resistance control, and the severe impact it will have on my cost of production and consequently, my ability to compete with non-U.S. competitors.

There is currently a lack of alternatives for many of the products for which EPA is proposing cancellation. Guthion (azinphos methyl) is one of the more important products used on our farm. We currently use it to control carrot weevils on curly and Italian parsley. The carrot weevil will burrow into the roots of the parsley, destroying the root system and making the product quality unacceptable to my buyers. These varieties of parsley gross $15,000 to $30,000 per acre and are subsequently, among our more important crops. Pest control alternatives are available until our normal summer temperatures of 80 degrees Fahrenheit and above arrive. At those temperatures, Guthion is the only product that controls carrot weevil. EPA is proposing to immediately cancel Guthion use on parsley.

I, along with many producers throughout Ohio and the United States implement an integrated pest management program. This is a program designed to eliminate insect, disease and weed pest problems—not eradicate all pests. It means applying pesticides, fertilizers or irrigation only when the benefits outweigh the costs so we utilize less pesticide product and reduce a pest's likelihood of developing resistance to a particular product. In implementing an IPM program, we rotate the use of pesticides as well as consider other pest management options, including natural, biological, and cultural methods.

When our pesticide options are reduced to simply one product to control a particular pest on a specific crop, our IPM program suffers and its benefits decline. Dimethoate is a critical tool used on our operation to control aster leafhoppers on leafy lettuces. When we have been unable to spray due to weather difficulties, aster leafhoppers, which carry the infectious aster yellows virus, have destroyed two-thirds of our lettuce crop resulting in a $4,000 loss per acre. Dimethoate is the most effective, affordable product and the only chemical that effectively controls this pest. We have access to Sevin (carbaryl), the only other product available, but its repeated use results in resistance development among pests and kills all of the friendly predator insects upon which we depend. Killing our friendly, predator insects defeats the objective of an effective IPM program.

Dimethoate, which costs us $2.50 per acre, is also our first line of defense against aphid problems. An alternative for aphid control is Provado, a new, expensive product (at $15.00 per acre) we only use as a last resort. Because it leads to resistance development among aphids, we only use Pravado when the pest thresholds reach a critical point. This product is a good example of how a reduction in the selection of chemicals would easily result in resistance build up and a need to increase the pounds of active ingredient used.

Along with the rest of the agricultural industry, the vegetable sector—and my farm, are facing increasing economic pressure from competitors throughout the rest of the world. Once, my competitors were my neighbors in Ohio and other states. Now, it's Canada, Mexico, Chile, Central America, and for my neighbors growing apples—its China. Once upon a time, my costs and the prices I received for my products were both local. Now, my costs are local, but the prices I receive are global.

Today I must worry about not only how the exchange rate makes my products more expensive while my Canadian competitors relative price falls, I must also be concerned about having access to the same tools Canadian and other overseas growers have. As the broad spectrum, inexpensive, effective tools I currently use are taken away from me, it costs me significantly more to grow my crops. Yet foreign growers are still able to use these materials, further widening the competitive gap and my ability to compete in this global market.

The competitive advantage we are handing our international competitors through the current FQPA implementation path means we will continue to import more food where we have no control over how it is produced, nor how the workers that helped grow and harvest that crop are treated. Today, 0.7 percent of fresh fruits and vegetables are directly inspected. If no residue is found on imported fruits and vegetables, they are considered to have no residue. For U.S. products, if no residue is found, EPA still assumes that there is half the detectable level of residue on the food product. Under current FQPA implementation, zero does not equal zero, unless it's imported.

As a vegetable grower and a father of two children, I would be the first person to support this implementation if I believed it resulted in increased protection of our

food supply. If sound science shows that the environment or public health is at risk, I will be the first one to campaign for cancellation of a pesticide. However, if growers in other countries can still use the same products EPA bans me from using and the only hurdle our competitors have to cross is the residue testing at the border, how is food safety improved? Today we in the United States are in the midst of an obesity epidemic, especially among kids. What children's health needs is more fruits and vegetables, not a limitation of access to these nutritious foods or a reliance on imported fruit and vegetables over which we have no production control.

LIMITED ABILITY TO PARTICIPATE

As an agricultural producer I have been concerned with the lack of transparency on how EPA is conducting reviews and the process, or lack of, by which they are conducting these reviews. EPA appears to be rushing to complete the next phase of FQPA implementation, the cumulative risk assessment, by August 3, 2002. The pressure to complete this phase is brought by the need to meet the next statutory deadline in FQPA and to meet a deadline in a settlement decree with the Natural Resources Defense Council that was signed in the 11th hour of the Clinton Administration. Even at this late date, there is no indication what the bottom line of this risk assessment will be since none of the critical policy decisions—have been made. When I make decisions on my farm, I figure out how I am going to do something before I do it—not after.

There is no process by which stakeholders—particularly interested and impacted growers such as myself—can participate. If mitigating risk by eliminating products and uses is necessary, there is no process by which I can provide input on the uses and products that may have to be changed or lost and the consequences of such actions on the farmer. At the beginning of EPA's implementation of FQPA (January 20, 1997), then Administrator for the Office of Prevention, Pesticides, and Toxic Substances, Lynn Goldman said there would be no further data call-ins. Why a decision to restrict information was made was not clear but was indicative of a lack of transparency in the process and today a restriction on data call-ins is still a policy problem.

CURRENT CHALLENGES—CUMULATIVE RISK ASSESSMENT

I have already referenced that EPA is now moving into the next phase of FQPA implementation with its cumulative risk assessment. Through the risk mitigation already taken, and still being taken on individual products, we have already given up all the non-essential uses. What is left is left because those uses are absolutely critical. Now EPA is reviewing all of those uses again under its cumulative risk assessment. My concern with the policy approach EPA is taking fall into four primary areas: use of extreme measurements, indiscriminate use of extra safety factors, unreasonable confidence levels, and lack of a mitigation procedure.

A common-sense approach would dictate that:

1) EPA should avoid the constant use of extreme toxicity endpoints, population percentiles and added safety factors and combining these policies to unnecessarily restrict uses.
2) EPA should use an appropriate 100-fold safety factor that is protective for all population subgroups. EPA should avoid applying an unneeded additional safety factor that would add no real protection but would wipe out registered uses. EPA's assessment already is based on sufficient data and uses conservative assumptions; no extra factor is needed. The FQPA legislation gave EPA the right to judiciously apply extra safety factors, not apply it indiscriminately.
3) EPA should not use the 99.9th percentile as the basis for regulation. Regulating at the 99.9th percentile is no more protective of the health of sensitive members of our population, than regulating at a slightly lower percentile. Even the World Health Organization and the U.S. Food and Drug Administration does not regulate at this high a percentage. As my college statistics professors explained it, testing at 99.9 means you are including strange data that can't be corroborated such as a person that eats 10 pounds of grapes a day for several days.
4) EPA should explain what process it will use to address "risk", if any, resulting from a refined cumulative risk assessment.

I am not an expert in these particular areas. I am speaking about the above concerns from the perspective of a farmer who is observing that whole products are being retained or lost as a result of policy calls that EPA will make—not on scientifically reviewed approaches that are explained with data.

PROPOSED SOLUTION

I would not come before you today to share my concerns with the current implementation if I did not have suggested solutions. As I indicated previously, a reasonable approach to the implementation of the Food Quality Protection Act, based on real data and not theoretical risk should result in a workable outcome with few adverse impacts.

The American Farm Bureau Federation has extensive policy supporting a balanced, workable and transparent implementation of the Food Quality Protection Act based on sound science. Regulatory decisions must be made using reliable information and actual data; they must not disrupt agricultural production and not undermine our competitiveness in international markets.

I ask for a common sense approach to reviewing these products and ask EPA to understand how products are actually used. EPA assumes that I use the maximum dosage of crop protection product the maximum number of times on each of my crops. This is simply not true. My goal is to control the pest, not eradicate them from my field. Often times the very part of our crop that receives an application is never sold to the consumer.

As I discussed earlier, one of our major crops is lettuce. We apply Dimethoate, to lettuce plants when they are young and most vulnerable to aster leafhoppers. As the plant grows, the outer leaves that received the application at least twenty-one days prior to harvest, fall to the side and the lettuce is harvested without the outer leaves, which remain in the field. In this case, zero residue really means zero residue.

Transparency in the process of how EPA is reviewing these products and opportunities for stakeholder participation is vital. There needs to be a transparent process established with affected stakeholders' input before any risk mitigation is contemplated.

I ask for some consideration of how it is affecting the marketplace and agricultural production. FQPA has been in place and has undergone implementation for six years. I would ask that an analysis be done to ensure that we are not experiencing such unintended consequences as an increase in imported food or business failure of U.S. farmers with no additional improvement in the food supply. The safety of our population is not advanced if we simply reassign production to growers in other countries who do not fall under U.S. regulatory control.

I ask for your continued attention. Congressional involvement and oversight is needed to ensure that EPA's decisions are reasonable, well supported by reliable information and balanced in order to avoid disruptions in agriculture and our ability to compete effectively in international trade. Unless FQPA is implemented carefully and in a practical manner, it will cause great harm to agriculture and compound the economic difficulties that many farmers and ranchers are currently facing.

Thank you for the opportunity to address you here today.

Mr. GILLMOR. Thank you very much. Let me start with a question directed to both Mr. McClure and Mr. Zellers. EPA has already taken substantial steps to reassess many OP tolerances, including working with companies to voluntarily cancel the uses of many of these products or to impose new risk mitigation measures that impact how the products can be used.

In your view, for products which the Agency has already substantially restricted, such as methyl parathion, Guthion, Lorsban, are there adequate and safer substitutes currently available that are as effective in controlling pests?

Mr. ZELLERS. I will go ahead and answer that, Mr. Chairman, in regard to Guthion, if we lose that product for the particular use that we have it for, we do not have an adequate replacement. I talked to one of our growing personnel in our farming operation, he told me the other product will work about 60 percent effective when the temperature is under 75. When it goes to 80, it goes to about 20 percent. During the summer in northern Ohio, 80 degrees is an average temperature. So in fact for that particular compound, we do not—if we lose the tolerance for curly parsley, we do not have a replacement in place right now.

Mr. GILLMOR. Terry.

Mr. MCCLURE. I guess from a grain perspective—and Dr. Brown alluded to this—ethyl bromide, which is the main chemical that we use for stored grain, there is no replacement for that. Sometimes the weevil and insects actually come from the field and are not a result of bad storage practices, they actually come in with the crop. Especially in wheat, it really renders that wheat useless, because the heart is eaten out of that wheat and it renders it useless for milling and there is no known replacement for that right now. That's a huge concern in the grain industry, certainly in this part of the country.

Mr. GILLMOR. If I could once again direct to either or both of you. In your statements, you both not only highlight the problems and the concerns with FQPA, but you also propose solutions to help guide implementation. I very much appreciate both the time and the thought that you have put into this. I know that being a farmer is a full time job, or more than that, and that you are willing to take the time to testify today is I think a great service that you are both doing for your communities.

One of the recommendations in your statement is for more transparency in the FQPA process, and it is an issue that I have raised with EPA. In particular, how would more transparency be of help to you and what is it about the FQPA process that is not adequately out in the open?

Mr. MCCLURE. Well, many times, Mr. Chairman, by the time we hear about the process, especially down to our individual farmers and how it is going to affect us, it is already in the process of being changed and implemented. Some of these things are moving at a speed that we are not getting the input that we would like to have on it.

Mr. ZELLERS. An example was given, and I don't recall, one of the other people that provided testimony here made the comment about the initial on cumulative coming out maybe the end of May or in June. When you are talking about an August 3 deadline, if they have a 90-day comment period or even a 30-day comment period to assess that information before stakeholders such as ourselves, the timeliness of that is not possible. So I would argue myself that the process has not been transparent enough.

And I might say, obviously the science of cumulative is complicated but the deadlines—EPA is forced to operate within the deadlines and one thing that we have often talked about, to achieve a good science base and to allow the science policies to be reviewed and not to come—you know, the cart in front of the horse, it is difficult with the time restrictions that EPA has and we understand that. But consequently that does not result in a transparent process.

Mr. GILLMOR. Okay, thank you. Let me go to Ms. Schmenk. As an important business operating here in Ohio, I think the viewpoint of Scotts is very important to all of us, and in particular I am interested to get your candid assessment of how USDA and EPA are doing in implementing the Food Quality Protection Act. In your statement, you indicated some serious concerns about FQPA and my question is are those concerns related to the law that was passed in 1996 or are they more relevant to EPA and USDA's im-

plementation of the law. So put another way, is the problem with the statute itself or is it with the way the statute is being applied and interpreted?

Ms. SCHMENK. I guess I would answer by saying a little of both. I think the law as passed left a lot open as far as the science had not been developed by the time the law was passed, so a lot was left up to would that science be developed in time to meet the deadlines that were included, and a lot was left up to the discretion of EPA.

As far as performance, if you would phrase it that way, of both EPA and USDA, I think one of the prior witnesses said we have seen I think less implementation problems with the new administration. I think we would applaud them for the openness and the willingness to include us in the process. I would though, however, say that I think Mr. Sharp, on behalf of EPA, talked about the six step implementation process and it is something that we saw when there was the deadline for August 1999, for certain things to happen, that process got compressed and I think really the last couple steps, which provided for stakeholder input, were rushed into a very short time period in order to meet that deadline. And we do have that same concern for this next impending deadline.

Relating to the USDA, I think Mr. Brown said that they feel that there is a need for more consumption data to better assess the risk and so I would just applaud him for acknowledging that, I am glad to hear him make that commitment and I would ask that you support him on that commitment and make sure that data is obtained before decisions are made.

Mr. GILLMOR. You mention in your statement a concern about overly conservative risk assessments. Some people hear that and they say well why should EPA not be overly conservative, we would rather have them make an error on the side of prevention rather than under-estimate risk. But is that too simplistic and could you describe some of the consequences of using overly conservative assumptions?

Ms. SCHMENK. I think it is too simplistic and I think Mr. Zellers talked about his two children, I have two children myself, a 4 year old and a 10 year old, and you know, they are very near and dear to my heart and I would like them to be protected and I want the laws of our country to protect them. But I think what we have seen is when you use—or when the EPA uses the default assumptions instead of actual data, it does result in more risk being assessed than is in reality there. I think Mr. McClure talked about assumptions where, for example, my industry, an assumption if a child is exposed in several different ways, if all of that is added together then, that child would be seen to be very much at risk. When that is not the reality of how things happen.

I think another default assumption that is being used to assess risk for children on turf, there is an assumption, a hand-to-mouth scenario that they will ingest 5 percent of pesticide residue and actual statistics show that it would be far less than that. So again, if we can encourage the EPA to wait for that actual data and to use it rather than these default assumptions, I think we will have a much better chance of retaining uses of these important pest control products.

Mr. GILLMOR. Thank you. Mr. Marquette, you are here today to provide yet another perspective on FQPA and that is of the exterminator who relies on products like chlorpyrifos to treat termites, for instance. But in fact, chlorpyrifos was a product that became more widely used because of EPA's decision years back to remove chlordane from the market. Now it seems that the writing is on the wall for this product as well and you mentioned synthetic pyrethoids as a substitute. Can you tell me how these products work differently from chlorpyrifos and whether they can perform as an adequate substitute should EPA further restrict uses of the OPs after it completes its cumulative exposure assessment?

Mr. MARQUETTE. Thank you very much, Mr. Chairman. The loss of the OPs to the structural pest control industry has been overwhelming. Two things factor in with the loss of chlordane and the more use of the chlorpyrifos at that time is that the OPs, when we are protecting homes against termites and other wood destroying insects, wood boring—reinfesting, wood boring insects—those termites will take and—they cause more damage to homes and business and structural pest control than all the fires and natural disasters with tornadoes and hurricanes and everything in the United States and it is a constant year-in, year-out more damage.

With the OPs, we did have at that time, products that were able to take and use for long lasting protection. With the synthetic pyrethroids, it does not seem as we are going to take and have that long term protection for our customers' homes and residences.

We have—in essence, the writing has been on the wall for the OPs for our industry and it has really affected us tremendously. Fortunately, there is research and we are finding other products that we may turn to. We are not sure quite how effective and the efficacy as well as the length of those products are going to last for our customers to protect their homes and protect their health. But the synthetic pyrethroids, the pyrethroids and other products that are available to us now, we must maintain to continue the health and protection for the community as a whole. Not only do we protect against the termites, but we are looking at health risks from mosquitoes, rodents, everything.

Mr. GILLMOR. What do you think you will use in place of Ficam this year and will it be effective?

Mr. MARQUETTE. It is a toss up right now and I will tell you what, Ficam for the last 22 years has been an absolute perfect staple in our arsenal of tools if you want to say. When we get—I do not feel right now that there is a product out there that is effective, with assurance that we are going to get control on stinging insects. We had a child development center on one of the hospital grounds last year that had 37 different wasp nests on this ground. They had several—I think it was four different children under the age of 5 that were stung. We went in, effectively removed those nests without any jeopardy to the children. To see a child be stung in the way that they do and the allergic reactions that they have to them, far outweighs the loss of that product. And honestly, we will turn to the pyrethroids for control, they do not last as long, it is a fast acting chemical with a very short residual life.

Mr. GILLMOR. Let me, for our last question, go back to Mr. Zellers and Mr. McClure. One recommendation you make is for

Congress to increase USDA funding to allow it to better participate in the FQPA process and reassessment. That is an issue I raised with Dr. Brown as well. In what ways do you believe U.S. EPA and USDA cooperation may be breaking down or might be improved?

Mr. ZELLERS. Mr. Chairman, it is not maybe a matter of breaking down, but he alluded to some data that is difficult to arrive or they maybe do not have good data, talking about 12 staff people and I believe $80 million and while that seems on the periphery a lot of money and 12 staff people, it would be interesting to know how many people at EPA are working on the issue. As we feel like USDA—as farmers, they should be our partner in this, they should be our representative in seeing that when there is potential loss, that even regionally within this country, that there is not shifts of production because one product is lost for use just in that area that might not be used because of different pests. So I would say, No. 1, it seemed like USDA from the start was behind the curve on this and that was more so in the previous administration, and I think it is just a difficult process to play catch up in and it seems as if they do have a limited staff and budget to do so and a limited timeframe. If they are provided data on behalf of us, it is not adequately occurring.

Mr. MCCLURE. Well, I would just like to reiterate, if you are low on budget, we want to make sure there is plenty of testing done. If one of our farms has to quit raising some of the fruits and vegetables we have here, we cannot store grain any more because adequate testing was not done before these chemicals are just done away with, that is not only a big hurt to us as producers, but actually I think it is damaging to the consumer, because as we have alluded to many times in our testimony, then we have to go back to imported goods that do not always have the same production requirements that we do here and are allowing the chemicals to be used that we may be banning. And is that actually helping the consumer? I do not think so.

If I might, Chairman Gillmor, you know, common sense is pretty important in life and as we go to this 99.9 percentile and ten times ten and some of the things I have read about is maybe eight pounds of grapes a day to a toddler, maybe to my 5 year old, and along at the same time, two quarts of apple juice and two quarts of grape juice. I might add, that child has got a lot bigger problems than any chemical residue if they are eating these volumes to hit the limits that we are talking about. Common sense has to be used in all things.

Mr. GILLMOR. Just as an aside, I do not want to pick on EPA because they do a great job in a number of ways, but there was an instance that I recall about 10 years ago where there was an atrazine limit proposed and I had my staff calculate how much water you would have to drink to hit that threshold and we ascertained that if you drank 38 bathtubs full a day for an extended period of time, you were in serious trouble.

I do want to thank all of the witnesses and I want to thank USDA and EPA who made a special effort this morning to be here. We appreciate your input.

And as I mentioned earlier, all of your full statements are in the record and the record will be held open for 10 days for anything further that you want to submit.

We thank you very much. Meeting adjourned.

[Whereupon, at 12:13 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF CROPLIFE AMERICA

CropLife America commends this Subcommittee and Chairman Gillmor for holding this oversight hearing on EPA's implementation of the 1996 Food Quality Protection Act. It is the first such hearing under the jurisdiction of the Commerce Committee, and much has occurred since the Act became law almost 6 years ago.

CropLife America is the U.S. industry trade association representing basic manufacturers, distributors, and formulators of crop protection and biotechnology products. These companies serve American agriculture from basic research and development of new products that protect crops from pests, diseases, and weeds to the manufacture and marketing of these tools to our farmer customers. Our members include corporations and cooperatives, both large and small, which operate in a competitive and changing agricultural world.

We offer these comments jointly with our affiliate association, RISE (Responsible Industry for a Sound Environment), which represents our industry's specialty pesticides, largely for urban use. A direct linkage exists between markets and the regulatory environment for both agricultural and specialty pesticides. The market synergies of both sectors support common investment in product discovery, testing, and development. One company may discover, manufacture, and sell a a pesticide active ingredient in both markets, thereby spreading development costs to more products and benefiting customers on both sides of the equation. Together with RISE, we seek uniform and fair science-based regulation of all pesticide products.

As this Subcommittee knows, the crop protection industry provides essential inputs for American farmers that enable them to produce sufficient food to feed a growing and hungry world. Farmers need a variety of crop protection tools in order to select the best match for their individual farming operations and to fit integrated pest management programs. Their needs can vary widely from year to year, depending on crops grown, crop rotation schedules, weather, pest populations, and alternation of products to limit development of pest resistance.

Preventive use of specialty pesticides prevents human disease caused by insects and other pests. These EPA-approved products are necessary to avoid diseases, such as West Nile virus and other types of encephalitis carried by mosquitos, and serious property damage, such as caused by termites. Pesticides control a wide variety of pests, including biting insects, algae, bacteria, infectious microbes, weeds (such as poison ivy), and termites. Their use is essential to prevent children and others from risky and potentially life-threatening exposure to disease-carrying pests and unsanitary conditions. Specialty pesticides also enhance greenspaces, golf courses, and lawns; keep rights-of-way clear of burdensome weeds; and help control invasive species.

Our industry has a long history of government regulation according to up-to-date, peer-reviewed scientific principles and reliable data and information. The basic toxicity studies that we conduct on pesticides are closely parallel those initially conducted on human drugs. In addition, we evaluate the fate and impact of our products in the environment, a proven process that is continuously being refined to better ensure their safe use. When we actively supported repealing the Delaney provisions in FFDCA in conjunction with passage of FQPA, it was because we, along with the scientific community, recognized that the zero risk Delaney standard for carcinogenicity was not based on accepted scientific principles.

FQPA requires EPA to impose new safety standards for pesticides and to reevaluate the maximum pesticide residue levels permissible on food. We support the law's fundamental goals, including enhanced protection of infants and children. EPA's implementation of FQPA determines the ultimate fate of many crop protection tools. To avoid unnecessary disruptions in pest control programs and for reasons of precedent, the implementation of FQPA must be balanced, reliable, and based on sound scientific principles.

With passage of FQPA in1996, EPA was required to implement a new law that was ahead of the science. FQPA did not provide any transition period for EPA to develop the new science needed to implement the Act. To meet FQPA's new safety standards, new scientific questions had to be answered and new data was called for, which created policy and data gaps. EPA needed a transition period to issue imple-

menting regulations, develop and issue science policy guidance, gather needed data, and develop appropriate risk assessment models before making decisions.

As a result, the Agency has been forced to carry out the new law while developing its plans, policies and new scientific approaches, AND meeting statutory decision deadlines. EPA is still developing its scientific approach to cumulative risk assessment, with decisions expected in early August 2002. Since 1996, despite EPA efforts to the contrary, implementation has been confusing, inconsistent, and often arbitrary. The result has been an unpredictable evolving process, with registrants and users attempting to meet unclear requirements, and pesticide uses lost unnecessarily.

During the past 6 years, EPA has grown to recognize the importance of implementing the 4 principles outlined in Vice President Gore's 1998 directive: sound science, transparency, reasonable transition, and stakeholder involvement. CLA strongly supports these principles as the foundation for implementing FQPA. In some areas, the Agency has made steps in the right direction. In other areas, much progress is still needed.

EPA Actions on August 3, 1999

EPA's actions on August 3, 1999 (the first statutory deadline for tolerance reassessments) were unacceptable, since the Agency ignored the Vice-President's commitment to sound science, transparency, orderly transition, and stakeholder involvement. Although the Administration proposed and published a clear implementation process, EPA failed to follow its own plan, abandoning transparency and transition/mitigation discussions for farmers and other users. The Administration jumped to decisions without the benefit of public comment on still-evolving science policies that very likely would have changed the results upon which EPA based decisions. EPA also refused to review and consider important data submitted to the Agency in making those decisions.

Shortly before August 3, 1999, EPA top management decided to create significant "examples" of risk mitigation for two organophosphate (OP) insecticides. This decision was set and the course charted to meet that goal, notwithstanding the fact that:

a. Not all scientific studies on the two subject chemicals had been fully evaluated by EPA and incorporated into the risk assessment.
b. More science studies are in progress.
c. "Science policies" that could significantly impact the risk assessment of the two subject chemicals have yet to be finalized by EPA.

Under the outright threat of cancellation of these two OPs and the concern for other products, the registrants were forced to "negotiate" and found themselves part of a rush to judgment in order to contribute to a perception of further achievement by the August 3 deadline. This occurred *despite* the fact that the Risk Assessment and Mitigation Phase VI step that was developed by the Tolerance Reassessment Advisory Committee (TRAC), with full endorsement of USDA and EPA, would be totally subverted in the process.

Mr. Chairman, while we commend the earnest and hard work of the companies that "cooperated" in negotiating last minute agreements with EPA to save many uses for these two chemicals, in large part to help avert a "food scare" based on perceptions and threats, the Vice President's principles suffered a serious blow—and sound science took a back seat to political science.

We strongly urge this Subcommittee to ensure that EPA not to repeat the past, and insist that the Agency follow an orderly, open and predictable process, based on completed defensible science policies and adequate public participation, in preparation for making its tolerance reassessment decisions expected this August 3.

SCIENCE POLICIES

EPA has taken steps in the right direction by using a probabilistic model in aggregate and cumulative risk assessment, and by continuing to use more refined exposure data in some cases. EPA is increasingly using more realistic data about actual percentage of crop treated with an individual pesticide compared to the Agency's earlier FQPA practice of assuming that 100% of a crop is treated, when that is not the case. EPA has also made incremental progress on models to estimate pesticide residues in drinking water. Industry is working jointly with the federal government to develop modeling procedures that promise considerable improvement for estimating exposure to pesticides through drinking water.

However, the impact of the cumulative risk assessment on the availability of vital pest control uses depends in large part on how EPA chooses to address key science policy issues which are currently unresolved.

FQPA Uncertainty Factor

EPA has not yet indicated if they intend to apply the additional 10x uncertainty factor, specified by FQPA, to the overall OP cumulative risk assessment. The additional FQPA uncertainty factor was intended to account for potential pre- and postnatal toxicity, and completeness of data on exposure and toxicity to infants and children. In the case of the organophosphates, the available data are sufficient to show that toxicity and exposure to infants and children are adequately understood in the current risk assessment. Therefore, there is no need for the additional FQPA uncertainty factor to be applied in the OP cumulative risk assessment.

If EPA estimates pesticide dietary exposure at the 99.9th percentile of the population, as it has done in aggregate risk assessments for individual pesticides, risk mitigation may appear necessary where it is actually unneeded to provide protection. No other regulatory agency in the U.S. or elsewhere in the world regulates at the 99.9th percentile. In many individual chemical assessments, the choice of even a slightly lower percentiles (e.g. 99.5th) would have meant no risk mitigation measures would be necessary. The same will likely be true for the cumulative assessment. While statisticians find no practical difference between even the 99.9th and 97.5th percentiles, If EPA regulates at the 99.9th percentile, uses and products could be lost without additional protection of public health.

According to joint policy of CDC's National Center for Health Statistics and USDA's Food Surveys Research Group (attached), the available dietary data used in pesticide risk assessment should not be used to estimate extreme percentiles of food consumption, as EPA has done. Based on recommendations of this policy, a minimum sample size of 400 would be needed to reliably estimate the 95th percentile, but at least 20,000 samples are needed to reliably estimate the 99.9th percentile. The sample size of USDA's Continuing Survey of Food Intakes by Individuals (used by EPA to estimate dietary consumption) falls far short of 20,000.

Use of Clinical Data

EPA has instituted an arbitrary and capricious policy against use of data from human subjects in its risk assessments under FQPA, under the guise of a review of the ethics and science of such studies. CLA vigorously disagrees with this policy and urges that it be rescinded.

It is unethical and immoral for EPA not to consider scientifically valid human testing that is already completed. To evaluate volunteers under appropriate scientific guidelines and then disregard valid scientific data insults the men and women whose valuable time and effort in these tests were intended to contribute to improving certainty in estimating pesticide risk and safety. Human testing is only necessary under limited circumstances, but when it is important, useful and necessary, it is not reasonable nor lawful for the EPA to find irrelevant excuses not to use such data.

By ignoring the human testing data, EPA potentially increases the public's risk. Recent independent scientific analysis of EPA's reference doses—the dose EPA has determined poses no appreciable risk to human health—for 38 chemicals, including pesticides, found that in 36 percent of the cases, human data would result in a lower, more cautious reference dose.

Further, human testing protocol inequities between EPA's pesticide registrations and FDA's pharmaceutical registrations are unjust and must be rectified. At least a dozen pesticide molecules are registered as components of pharmaceuticals—that have gone through extensive human testing, which is required for FDA drug registration. For example:

- Streptomycin and oxytetracycline, both antibiotics used in humans, are also pesticides used to treat bacterial diseases of fruit trees;
- Lindane, malathion, and pyrethrin, used in lice shampoos to treat lice infestations, are also in crop insecticides;
- Thiabendazole, used to treat parasitic worms (such as trichinosis) that afflict humans, is a component of certain fruit and vegetable fungicides;
- Sulfur, used to treat skin diseases, is a widely used fungicide; and
- Warfarin, a blood thinner for treating cardiovascular disease, is used in rat poisons, which are regulated pesticides.

Pesticides are as beneficial to humans as are pharmaceuticals. Pesticides help safeguard public health by controlling or eliminating pests such as cockroaches, associated with asthma; mosquitoes, which carry West Nile virus, encephalitis, and malaria; ticks, which transmit Lyme disease; and termites, which destroy houses, barns, and businesses. Pesticide crop protection prevents losses from damaging pests, competing weeds, destructive fungi, and devastating plant diseases. The resulting increases in crop yields and lower production costs provide us with the benefits of safe, nutritious food that is abundant and affordable.

Exposure Assessment

Inappropriate Comparisons: In EPA's OP cumulative risk assessment the Agency is improperly mixing exposure and hazard information. Standard risk assessment procedures compare acute hazard (toxicology) data to acute exposure data, and chronic hazard data with chronic exposure data. In this assessment, EPA is comparing chronic hazard data with acute exposure data. In order to obtain accurate scientific results, EPA must compare the chronic hazard data with chronic exposure data, and acute hazard data with acute exposure data.

Failure to Use Reliable Data

Default Assumptions—Under FQPA, many pesticide uses have been cancelled unnecessarily due to use of default assumptions in lieu of real-world data, and in some cases even available data was not used in decision-making. FQPA expressly requires EPA to use "reliable" information, which makes EPA's use of "default" assumptions inappropriate. Although EPA has incorporated registrant-generated data into its risk assessments, the Agency still uses some default assumptions rather than available, reliable data. There are also incidents where EPA is picking and choosing or completely ignoring reliable data.

For example, EPA's OP cumulative risk assessment over-estimates residential exposure, relying on several default assumptions. The result is that the "risk cup" is filled unnecessarily, which threatens unnecessary loss of pesticide uses. In anticipation of the need for additional real-world data, two industry task forces have been generating data on residential non-dietary exposure and have kept EPA informed of their progress. Even so, in some cases EPA has proceeded with risk assessments without using or waiting for data generated by the Residential Exposure Joint Venture and the Outdoor Residential Exposure Task Force. These data should be incorporated into EPA's final OP cumulative risk assessment to ensure the most accurate estimates of actual exposure.

Reliable data, not default assumptions, must be used to ensure that the risk cup is not filled with unsubstantiated "theoretical risk." Where adequate data do not exist, EPA must seek the data.

Cumulative Risk Assessment: Additional Analytical Software Tool

CropLife America has developed the Cumulative and Aggregate Risk Evaluation System (CARES), an alternative computer software model for conducting risk assessments under FQPA. CLA urges EPA to use this model in performing its cumulative risk assessments. Further, EPA should compare results from CARES to those from Calendex™, proprietary software currently used the Agency to conduct the OP cumulative risk assessment.

The developers of CARES have conducted a cumulative risk assessment of the OP pesticides, comparable to EPA's preliminary OP cumulative risk assessment. The CARES software package was submitted to EPA last week and to members of EPA's Science Advisory Panel (SAP) for review in April, along with its OP cumulative risk assessment. Recommendations to EPA regarding EPA's use of CARES are expected from the SAP shortly thereafter.

CARES provides a number of advantages over the Calendex™ model currently used by EPA:

- It is open and publicly available. (EPA had been criticized for using a proprietary model in its cumulative risk assessments, and has acknowledged the need for an open model);
- It provides improved and more realistic means of constructing model populations that take into account seasonal patterns of exposure.It has the capability of readily identifying the most likely sources of risk in a cumulative risk assessment. (EPA's current software used for CRA cannot easily identify "risk drivers," though EPA says that it is developing a process to identify them.)
- It can run multiple "what-if" scenarios, to test the effects of various risk mitigation scenarios.

EPA has separately funded, in fits and starts, development of the LifeLine software package, and just recently announced award of a contract for cumulative risk assessment of the OPs using LifeLine. However, the enhancements required for LifeLine to accomplish the cumulative risk assessment are far from complete and will not have been subjected to peer review by the SAP or elsewhere prior to the August 3 FQPA deadline.

PROCESS ISSUES

Cumulative Risk Assessment (CRA) of the Organophosphates (OPs)

In anticipation of its August 3, 2002 decisions, EPA has indicated that it plans to follow a broader and more extensive public participation process than it did before the last FQPA decision deadline of August 3, 1999. Congress should hold EPA to its word.

EPA plans to issue a revised draft OP cumulative risk assessment with additional opportunity for public comment, although the June 1 issue date will unduly limit the time for public review and Agency decision-making.

For this revised CRA to be meaningful given the upcoming August 3 deadline, it must include determinations on: (1) use of the percentile of exposure as a threshold for regulation (99.9 percentile issue); (2) use of the FQPA uncertainty factor; 3) use of appropriate toxicity data for acute and chronic exposure evaluation; (4) identification of any "risk drivers;" and (5) if mitigation and transition will be needed. EPA should convene the CARAT Cumulative Workgroup to discuss the revised draft CRA and provide input. EPA should establish and inform stakeholders of its public process to manage the risk cup if it overflows.

The Agency must be held accountable for announcing its percentile of regulation, toxicity/exposure comparison, and safety factor policy decisions as well as identifying risk drivers in its upcoming revised draft CRA.

Science Policies Should Be Completed Before Decisions Are Made

Final versions of all EPA's science policies that drive FQPA decisions have been slow in coming, and the last ones are not yet complete and available to the public. EPA has made FQPA decisions before finalizing and publishing these critical science policies on many compounds. Stakeholders, including farmers and other customers, often have been left guessing what policy approach the Agency will take, and policies have been inconsistently applied in various Agency decisions.

Mitigation

EPA's plans and process are unknown regarding any mitigation measures that may be needed due to the upcoming August 3 decisions. EPA has informally indicated that the most convenient way may be to drop uses for specific products rather than spreading use reductions or eliminations more broadly across products. Lack of a clear process encourages speculation and deep concern among farmers, other users and registrants. How will EPA determine benefits? How will the Agency weigh benefits against risks, and prioritize some benefits over other benefits? The CARAT Cumulative Workgroup should have the opportunity to meet to discuss and develop and recommend an orderly plan for transition and mitigation to the Agency.

Grower Involvement

EPA should involve growers earlier in the FQPA decision-making process. Currently, growers are contacted during mitigation talks, after risk assessment has been completed. Growers could have more meaningful involvement and provide additional reliable information about actual use and application, for example, if earlier consultation occurred.

Data Requirements

Congress incorporated into FFDCA provisions from FIFRA that prescribe how EPA should update and publish the new data requirements for registering pesticides and how registrants should be given adequate time to collect the new data on old products and make it available to the Agency. This process worked very well in updating product databases for reregistration, as mandated by the FIFRA 1988 amendments. After FQPA passed, we petitioned and repeatedly urged the Agency to fully utilize these data updating provisions of the new law. To date, EPA has shown little indication that the use of these product-specific data-development provisions is a meaningful part of their implementation process.

EPA should acknowledge that sound science requires good data and validated methodologies, which require time to develop. The Agency has not identified, via formal guidance and rulemaking, which tests registrants must conduct to generate data for EPA risk assessment required by FQPA. Testing guidelines, protocols and methodologies continue to be a moving target. By leaving scientific questions unanswered, incomplete data can lead to imposition of the FQPA uncertainty factor and consequent loss of pesticide uses. Registrants need clear Agency directives to provide specific data in support of product registrations and tolerances. For example, since registrants have not had clear guidelines from EPA on how to conduct developmental neurotoxicity (DNT) tests, some companies have completed the tests, while others are working with EPA to determine the best methodology to use. EPA is

using DNT data in the OP cumulative risk assessment, but lack of data from studies still in progress under data call-ins according to FIFRA procedures should not be used as a basis for loss of pesticide uses.

EPA should issue updated testing guidelines (40 CFR part 158), as required under Section 3 (c)(2)(a) of FIFRA to clarify and specify the kinds of data required to support the registration of a pesticide. Testing guidelines and data requirements for FQPA's tolerance reassessment must be clear for fair implementation of FQPA, so the regulated community and customers understand how to comply with the Act.

Advisory Committees

Since the enactment of FQPA, stakeholders have advised EPA on implementation through three successive advisory committees: the Food Safety Advisory Committee (FSAC), the Tolerance Reassessment Advisory Committee (TRAC), and the Committee to Advise on Reassessment and Transition (CARAT). They continue to provide important opportunities for public understanding and input. This should be continued through establishment of a *permanent* Pesticide Advisory Committee, jointly chaired by USDA and EPA, to advise the agencies on FQPA implementation.

Conclusions

In conclusion, there are improvements needed as EPA implements FQPA. CLA's summarized concerns on FQPA implementation by EPA are:

- EPA has often created policy "on the fly" to implement FQPA. This has involved several major, sudden capricious reversals and decisions on individual products and on broader policies, without informing or consulting stakeholders. Instead of giving ample time to generate new data called for by FQPA, EPA penalizes pesticides for not having data . . . data EPA hasn't even required!
- EPA's estimates about pesticide exposure have often been inflated by unsupportable assumptions, judgments, and models that do not resemble reality. This causes EPA to significantly overestimate actual risk to farmers and consumers, forcing unnecessary cancellation of uses and products.
- EPA has ignored credible, reliable data about individual pesticides, and has selectively used questionable data from studies to help make what is often a political case against products.
- EPA has not yet published current comprehensive data requirements needed to determine whether a pesticide meets FQPA's new safety standards. As a result, pesticide companies must frequently guess which tests to conduct, and these may or may not satisfy EPA reviewers.
- EPA has made pesticide decisions before finalizing and publishing the science policies upon which the Agency said that it would base decisions.

Our industry remains committed to Vice President Gore's four principles, and strongly urges this Subcommittee to ensure that EPA fully follows them in its implementation of FQPA. It is the only means by which we can have a fair, consistent, and predictable regulatory process. And that is essential if we are to maintain today's safe technologies and have the incentive to discover tomorrow's innovative new technologies. They will be essential if America is to lead the way in serving three square meals a day in the coming century to a troubled and hungry world, enhancing our greenspace, and protecting public health from disease-causing pests.

PREPARED STATEMENT OF THE FQPA IMPLEMENTATION WORKING GROUP

The FQPA Implementation Working Group (IWG) appreciates the opportunity to present its views to the Subcommittee on Environment and Hazardous Materials in this oversight hearing on the manner in which the 1996 Food Quality Protection Act (FQPA) is being implemented by the U.S. Environmental Protection Agency (EPA) and its Office of Pesticide Programs (OPP). The IWG is a coalition of farm, food, pest management, manufacturing, and consumer protection and health benefit industry organizations that have joined together to address and respond to the requirements of the FQPA, which amended the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The FQPA introduced a number of new concepts into the regulation of pesticides that have required interpretation. The law was enacted in a rather unusual manner. The House committee bill was approved in a very short markup session, quickly approved by the House, and approved by the Senate in a quick floor vote without any committee hearings. The result of this process was that there is much less legislative history than is usual for a law of such sweeping importance. It made extremely important changes in the way EPA was required to make decisions about the acceptability of pesticide residues on food, but left to EPA the job of filling in not just

the details, but much of the basic concepts. Moreover, the law became effective upon enactment, and established a demanding set of deadlines for completion of reassessments of all the then-existing pesticide residue tolerances. Accordingly, EPA has had to make policy decisions about how the law should be implemented while it was also making actual decisions under the law, instead of being able to first make the policies and then carry them out.

For example, the FQPA requires that in deciding whether the tolerances for food residues of a particular pesticide were acceptably safe, EPA must now consider exposure not only to those food residues, but also to the "aggregate" exposure that might result from drinking water residues or from use of the pesticide in or around residential areas, to the extent that EPA had "reliable information" about such exposure routes. But Congress did not spell out what the "reliable information" provision actually meant. Data to assess quantitatively the amount of exposure from residential uses and from drinking water had never been required before for the overwhelming majority of pesticides. EPA had to choose whether to (1) include estimated exposure by these routes in its tolerance reassessments immediately, before the data could be gathered, knowing that this would require massive reliance on assumptions, or (2) conduct its initial tolerance reassessments of exposure by the food route, issue orders to registrants to gather and submit the needed exposure data, and conduct a second assessment when the data were received. EPA early took the position that it would use assumptions and not wait to obtain new data. And in its early announcements, the Agency indicated that this use of assumptions about non-food exposure could result in decisions that food uses of pesticides would have to be eliminated even though the food uses themselves did not pose unacceptable risk.

A second new consideration introduced by the FQPA is the concept of cumulative risk from compounds having a common mechanism of toxicity. While the FQPA merely says that EPA is to consider this potential when making decisions about the aggregate risk of a particular compound, the Agency has taken the approach that it must seek to quantify the cumulative risk in much the same manner as it calculates aggregate risk for individual compounds.

The third major change in the law was the requirement that when EPA decides what exposure level is acceptable, EPA should employ an additional safety factor for the purpose of ensuring the safety of infants and children unless it can conclude the extra factor is unneeded. Most of the 10,000 or so tolerances to be reassessed were initially granted by comparing the food residue levels to an acceptable value calculated by finding a no-adverse-effect level in animal testing and dividing it by a safety factor of 100 that is designed to account for possible inter-species and intra-human sensitivity differences. The FQPA gives EPA broad discretion and essentially no guidance on how to decide whether to apply or remove the additional 10X factor.

By late 1997 and into early 1998 it became clear that EPA was taking positions on these policy/interpretation issues that would lead the Agency to conclude that exposure was much too high and that many tolerances would have to be revoked. Moreover, the Agency had not developed a systematic approach for making its policy decisions openly after stakeholder discussion. The concerns of growers and other stakeholders led to demands by Congress and ultimately a directive from the White House for the creation of a more open FQPA policy-generation process. This led to the formation of a Tolerance Reassessment Advisory Committee (TRAC)) co-chaired by high officials of EPA and the Department of Agriculture, and the discussions by the stakeholder members of that Committee convinced EPA to publish a series of proposed "science policy" documents on various FQPA topics and to take comment on them.

The FQPA Implementation Working Group was formed in early 1998 to provide analysis on these policy matters and to make known the importance of developing policies that are sensible. We submitted to OPP in June 1998 a set of policy papers collectively titled "A Science-Based, Workable Framework for Implementing the Food Quality Protection Act" (commonly referred to as the Road Map). It included an overview section (a copy of which is attached) and a series of detailed issue papers on the following topics:

- "Dietary Exposure;"
- "Drinking Water Exposure;"
- "Residential Exposure;"
- "Aggregate Exposure;"
- "Common Mechanism and Cumulative Effects;"
- "Choice and Use of Endpoints in Risk Assessments of Cholinesterase Inhibitors;" and
- "Legal Issues."

In a number of areas the implementation of the FQPA by EPA has improved since 1998. The TRAC met from mid-1998 through the end of 1999, even though its envi-

ronmental and consumer activist members resigned in protest in April 1999, claiming that it was wrong for EPA to develop policies before taking action. A second advisory committee, the Committee on Reassessment and Transition (CARAT) was formed and has been meeting since mid 2000. We think that these discussions led EPA to conclude that it is in the Agency's interest to make its process much more open than it had been, to seek outside opinion on policy choices, and to seek to make more use of realistic estimates and less use of worst-case estimates.

Certainly there has been an increased willingness to discuss issues instead of simply announcing decisions. EPA has made an effort to explain its approaches and to discuss issues with stakeholders, and has now issued revised versions of almost all of the 20 or so proposed science policy papers that were generated by the TRAC process. The IWG has submitted extensive comments on the proposed documents.

EPA has moved away from several of its most conservative worst-case assumptions. It also has more data to work with on residential and drinking water exposure than it did a few years ago. Although it still lacks the information it needs to make good quantitative estimates of exposure by those routes, it now is able to make better "screening" estimates. For instance, in the cumulative risk assessment now underway for the organophosphorus (OP) compounds, EPA was able to use modeling and monitoring information to conclude that there is no potential for significant OP exposure via drinking water.

However, there still are several areas where OPP is still taking positions that we think are fundamentally flawed. OPP has finally provided a response to the IWG argument that before a quantitative aggregate risk assessment can include exposure via residential or drinking water routes, the statute expressly requires the Agency to have "reliable information" on the likely levels of exposure via those routes. OPP now agrees that there must be reliable information, but says that that does not mean there has to be any information about exposure *levels.* OPP says that all it needs to know reliably is that there probably is some exposure at some level. We think this makes a mockery of the language and raises the very real possibility that OPP will use this doctrine to take action against crop uses in order to protect against completely speculative water residue levels or residential exposure.

Another area of continuing disagreement is whether the Congress contemplated that the additional safety factor discussed in the FQPA can be greater than 10x. We think that a reading of the legislative history show that the intent was that the factor could be "up to 10x," and EPA's pronouncements at and shortly after enactment certainly show that was the Agency's understanding then. More recently, however, EPA has changed its mind and now says the additional factor may be as large as the Agency desires.

OPP also is in the process of determining how to conduct the cumulative risk assessment of the important organophosphorus insecticide category. IWG has very recently filed extensive comments on OPP's draft assessment (copy attached). While we think several significant changes in approach are needed, we agree with much of the assessment and respect OPP's willingness to take comments and issue a second version, also for comment, before finalizing the assessment. We emphasized the need to resolve several major policy issues that have not yet been addressed. For one thing, OPP has not matched exposure periods with toxicity testing results properly when assessing risk. OPP is rightly concerned about single-day exposure peaks, but it was wrongly deriving its toxicity criterion from studies where doses were given every day over periods ranging from three weeks to two years. This makes it appear that the overall exposure is too high for some persons, whereas if the proper comparisons are used the allowable exposure is increased by a factor of 5 and all the expected exposures are within the acceptable range. For example, for children age 1-3, in the highest (99.9th) exposure percentile, the margin of safety goes from 51 (EPA would say 100 is needed) to about 250, well within the acceptable zone. What OPP should do is compare single-day human exposure with the results of single-day toxicity studies, and separately compare multi-day average human exposure with the results of multi-day toxicity studies, which is exactly what it has always done in all other safety assessments it has ever performed.

In addition, we argued that there is no basis for applying an additional "FQPA" safety factor with regard to the cumulative risk of cholinesterase inhibition posed by the OP compounds. Use of the standard safety factors (i.e., requiring an MOE of 100) will fully protect fetuses, infants, and children from any risks of cholinesterase inhibition from dietary exposure. Any effects that are associated with high doses used in animal experiments should be given no weight in this assessment, which should concern itself with the risks, if any, of the very low doses that would be associated with dietary exposure to OPs. EPA also should recognize the limitations of using information from toxicity studies on neonatal and preweanling rats in attempts to analyze effects in humans because of the differences in develop-

mental stages between neonatal rats and neonatal humans. There also is no justification for an additional safety factor with respect to the completeness of the toxicity database or our understanding of exposure potential.

Looking beyond the cumulative risk assessment for the OPs, EPA will face a series of challenging problems as it seeks to meet its second statutory deadline (it needs to complete its reassessment of the second third of tolerances by August 2002). After that, the remaining tolerance reassessments will pose further challenges. The IWG looks forward to contributing to the discussions that will allow EPA to develop logical, understandable policies based on sound science.

PREPARED STATEMENT OF JANE FORREST REDFERN, ENVIRONMENTAL PROJECTS DIRECTOR, OHIO CITIZEN ACTION

Congressman Gillmor and members of the committee, I want to thank you for your invitation to speak today on the Food Quality Protection Act (FQPA). I am Jane Forrest Redfern, Environmental Projects Director for Ohio Citizen Action, Ohio's largest environmental citizens organization.

I worked back in 1995 for the passage of FQPA and I have to say that with any legislation, there are good things and bad. One thing for sure is that the sky did not fall when this was being implemented.

Farmers are still farming. Consumers are still buying.

The Act has successfully set up a process to assess pesticides with the special vulnerabilities of infants and children in mind. I believe that was the goal—to assess the use and risk of pesticides to the public, environment, but especially exposure to children.

I want to comment on four areas of FQPA today which are of particular public health concern:

1. FQPA's implementation has resulted in an orderly process that removed or severely restricted the most toxic (ten) organophosphate (OP) insecticides. It has also reigned in the use of a number of cancer causing fungicides(iporidian) and several compounds that cause birth defects, and in general reduced the amount of highly toxic pesticides released into the environment (from agriculture and residential uses) with virtually no adverse impact on farmers and zero economic impact on consumers. FQPA did all this even as it prohibited any consideration of the economic benefits to farmers in regulatory decision making.

2. We have Pest Management Centers throughout the country looking at the use and alternatives of pesticides on all of our major crops and most minor crops. Through funding by USDA, we have studies being conducted on how farmers use pesticides, when and how much. They are also looking for pest management alternatives on how to reduce pest damage and reliance on pesticides. These are good things. If we have an understanding of pesticide use and alternatives, we can help and assist farmers on how to become more efficient, save money and reduce risk to themselves, their children, the public and the environment.

3. I see other actions and studies done by other entities right here in Ohio, due to FQPA: The Ohio EPA did a comprehensive study of water utilities and the levels of pesticides in drinking water.

This study then led to Ohio EPA requiring some of those drinking water suppliers with high levels of pesticides in their water to do additional testing of known pesticides more regularly. That led many water suppliers to look at their water systems and ways to reduce pesticides. For example: The City of Columbus worked with the Farm Bureau, Novartis and farmers to reduce or eliminate atrazine use in the Big Walnut Watershed, this has led to an overall reduction of use of powdered carbon to treat the drinking water.

The City of Bowling Green added a $2.3 million dollar water treatment plant due to high levels of pesticides in their drinking water supplies. The State of Ohio has had to look at pesticide use in Ohio and do planning and assessment of the pesticide use in Ohio.

Lastly, I support the implementation of the FQPA, but in some cases, the implementation is not as comprehensive, moving fast enough or meeting the legal requirements set out in the Act. The USEPA needs to do the following things to continue the implementation and to comply with FQPA fully: USEPA needs to add in a safety factor of at least ten in their calculations of risks for children and take into account the differences of diet, size, eating patterns and health status of the variable US population.

Children from rural communities and of farm workers are at higher exposure risk to agriculture use of pesticides, and need special consideration and deserve protection under the FQPA (1-9). There is evidence in the published literature that farm-

workers, and people living in farm communities, are at greater risk for certain kinds of cancer because of their exposure to pesticides (10-18) The Act requires protection of all children, even our own rural children.

USEPA needs to look at ranges for risk calculations instead of averages. The EPA must consider the fetuses, infants, and children exposed to maximum pesticide use rates, maximum pesticide food residues, and maximum water contaminant levels, because real children are exposed to these elevated levels in the real world. All children must be protected under FQPA.

In implementing FQPA, the USEPA needs to review all data submitted for the review, including published data, and not just data submitted by the chemical manufacturers, to make decisions that are protective and proved to be sufficient. If there is no data, USEPA needs to use the safety factor to be most protective as required by the Act.

The concerns raised in these short comments are only a small list of the considerations which are mandated by FQPA, and which are necessary to adequately protect the environmental and public health of American communities and therefore, I respectively submit comments for the record from: Children's Environmental Health Network; Consumers Union; Institute for Environment and Agriculture; World Wildlife Fund and Natural Resources Defense Council

Thank you for your time and consideration of my comments this morning, on a matter of protection of our health, the health of our families, and our environment.

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